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Effectiveness of a school-based multi-component smoking prevention intervention: The LdP cluster randomized controlled trial

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ABSTRACT

Objective. We assessed the effectiveness of the Luoghi di Prevenzione-Prevention Grounds school-based smoking prevention programme.

Methods. We undertook a cluster randomized controlled trial of 989 students aged 14–15 years in 13 secondary schools located in Reggio Emilia, Italy. The intervention consisted of the "Smoking Prevention Tour" (SPT) out-of-school workshop, one in-depth lesson on one Smoking Prevention Tour topic, a life-skills peer-led intervention, and enforcement surveillance of school antismoking policy. Self-reported past 30-day smoking of ≥20 or 1–19 days of cigarette smoking (daily or frequent smoking, respectively) was recorded in 2 surveys administered immediately before and 18 months after the beginning of the programme. Analysis was by intention to treat. The effect of the intervention was evaluated using random effects logistic regression and propensity score-matching analyses.

Results. Past 30-day smoking and daily cigarette use at eighteen months follow-up were 31% and 46% lower, respectively, for intervention students compared to control students. Taking into account non-smokers at baseline only, daily smoking at eighteen months follow-up was 59% lower in intervention students than in controls. Past 30-day smoking in school areas was 62% lower in intervention students compared to controls.

Conclusions. The Luoghi di Prevenzione-Prevention Grounds programme was effective in reducing daily smokers and in reducing smoking in school areas.

Introduction

Tobacco use by adolescents is a public health problem worldwide (WHO, 2011). Nicotine addiction established rapidly during adolescence (DiFranza et al., 2007) and early smoking uptake are related to the risk of dependence in adulthood and might be associated with reduced quit rates in later life (Chassin et al., 2000). According to the Global Youth Tobacco Survey in Italy in 2010 19.4% of boys and 21.6% of girls aged 13–15 years were current smokers, and 7.3% were daily cigarette smokers (Baska et al., 2009).

Schools are potential valuable setting for smoking prevention. Systematic reviews have not, however, provided strong evidence supporting school-based programmes for smoking prevention (Flay, 2009; Hwang et al., 2004; Skara and Sussman, 2003; Thomas and Perera, 2006; Tobler et al., 2000; U.S. Department of Health and Human Services, 2012; Wiehe et al., 2005). Some interventions appear to be more effective, particularly those that are interactive, those based on the social influences approach and those adopting a multi-modal approach (Flay, 2009; Skara and Sussman, 2003; Wiehe et al., 2005). Moreover, there is a suggestion for the effectiveness of peer-based interventions (Tobler et al., 2000).

School tobacco policies (STP) are also considered to be part of a comprehensive approach to prevent or reduce adolescent tobacco smoking (IARC, 2009; Lantz et al., 2000; Lipperman-Kreda and Grube, 2009), but the research is very poor and the evidence is weak and inconclusive (Galanti et al., in press).

There is an interest in studying the effects of multi-modal intensive interventions involving different school-based interventions (STPs, classroom interventions, peer training) together with community components providing of extracurricular activities (Brown et al., 2002; Dunn and Pirie, 2005; Perry et al., 2003).

Abbreviations: STP, School tobacco policies; LdP, Luoghi di Prevenzione-Prevention Grounds; SPP, Smoking Prevention Path.

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The Luoghi di Prevenzione-Prevention Grounds (LdP) study is a cluster randomized controlled trial designed to evaluate the effectiveness of a LdP programme, a multimodal intervention for the primary prevention of smoking targeted to students aged 14–15 year.

Methods

The LdP programme

The LdP programme and the trial design are described elsewhere (Bosi et al., 2013). Briefly, the LdP programme is based on 4 components:

1. The "Smoking Prevention Path" (SPP), a four-hour educational path delivered by trained educators (Lega contro i Tumori, 2008), in the context of a community Health Promotion centre. SPP delivered a set of education activities aimed at developing resistance life skills, and knowledge on the harmful effects of smoking. It is divided into four 40-minute sessions: a) a lab session: laboratory trials were carried out to separate different smoking substances using lab procedures; measuring particulate matter in tobacco smoking using a portable laser-operated aerosol analyzer; b) a computer session: every student filled in several 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) a 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, and beliefs; and d) an 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 classroom component consisted in a 2-hour in-depth school lesson on one of the SPP sessions. Teachers were previously trained in two 2-hour meetings.
3. A life-skills peer-led intervention: a group of self-selected 16–17-year-old peers were trained in three 2-hour sessions at school plus one meeting. They organized two 2-hour meetings in every intervention class, conducting a brainstorming on smoking, a discussion on positive and negative aspects of smoking, a creative writing session, and administered a questionnaire on health risks of smoking.
4. The enforcement of a STP: school staff established a working group, revised the school anti-smoking policy, enforced the smoking regulation and improved the non-smoking signs in school areas.

Trial design

This is a two-arm cluster randomized controlled trial with allocation ratio 1:1, where schools were randomly assigned to the experimental arm or to a no intervention condition (Fig. 1).

Sample size

With an inflation factor of 1.9 derived from an estimate of intra-class correlation coefficient calculated in grade participants in ESPAD surveys (Murray et al., 2004), assuming significance 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 3400 students (1700 per arm) would allow detection of a relative risk of about 0.70 (Hibell et al., 2009).

Selection and randomization of schools

Five secondary schools out of all the 25 secondary schools located in Reggio Emilia province (513,400 inhabitants in 2008) were excluded since they already participated in school-based smoking prevention programmes. The remaining 20 schools participated in the trial. Small school annexes of the participating schools with <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 size (number of students attending the first class in the 2008–2009 school-year), in order to obtain similar numbers of students in each study arm. In order to ensure allocation concealment, coupled schools were then centrally randomized to the experimental or control arm using a random-number generator. After randomization, three schools (2 vocational and 1 high schools) allocated in the control group refused to comply with their assignment to the control condition, since they wanted to actively implement the LdP programme. So, we included these control schools in the intervention condition but we excluded them and their demographically paired comparison schools from the main analyses, in order to maintain a randomized trial design.

Eligibility criteria for participants

The study population consisted of students attending the first class of secondary schools located in Reggio Emilia province, Italy. Exclusion criteria at the students' level were the own incapability to participate in the survey due to mental handicap.

Study operation and outcome assessment

The study was conducted in two waves: in the first wave in 4 pairs of schools the pre-intervention survey was conducted between December 2008 and May 2009, whereas for the remaining pairs of schools it 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 completion of the intervention.

Students in both arms had to fill in, during the class time, an anonymous questionnaire before and after the intervention. Questions covered demographic characteristics, cigarette use (lifetime and past 30-day tobacco); smoking of 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 of smoking, intention to smoke in the near future, smoking if friends offer a cigarette, perceived social norm and social acceptance of smoking, and 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

The questionnaires were anonymous and the link between pre and post-questionnaires was assured by 9-digit individual code generated by the student (Faggiano et al., 2008; Galanti et al., 2007).

Ethical aspects

The LdP study was approved by the Ethics Committee of the Local Health Authority of Reggio Emilia, Italy. Parents were informed of the intervention and have an opt-out option (Lega contro i Tumori, 2008).

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.

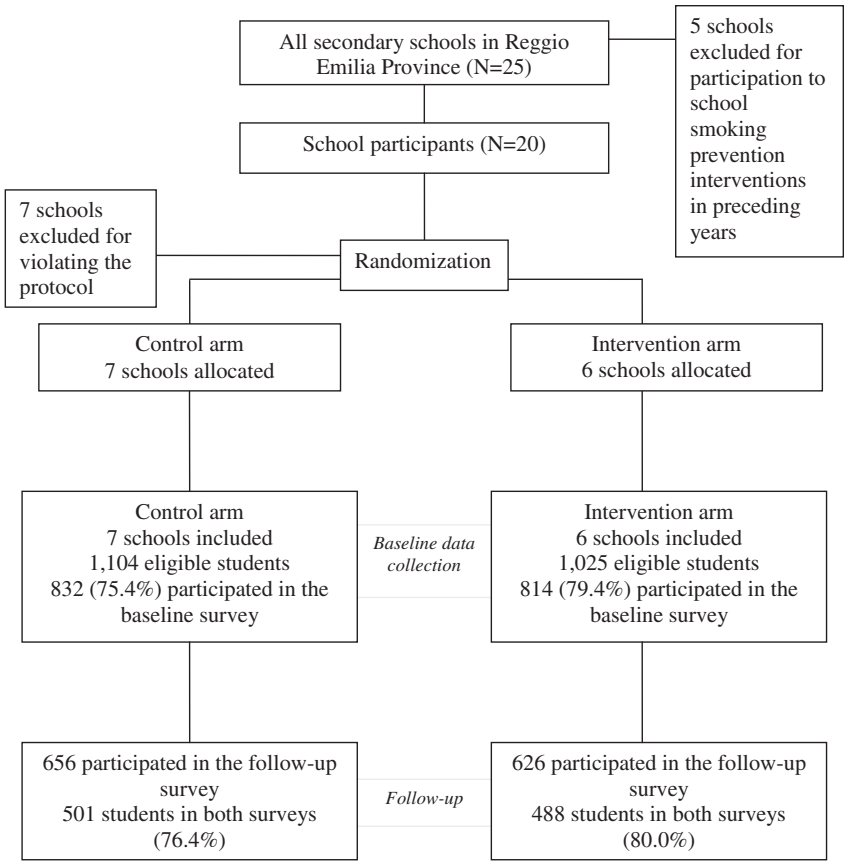

Fig. 1. Profile of the LILT-LdP study.

Analysis

We conducted a descriptive analysis of the baseline characteristics of recruited students in the participating schools. Differences in proportions were tested using the Chi-squared test. In order to take into account the hierarchical structure of the data, estimates of the intervention effect on smoking status at six-month follow-up were obtained with random effects logistic regression models with school as a random effect, and including as covariates past-30-day smoking at baseline and variables with different distribution between intervention and control groups (gender, type of school, date of the baseline survey, and days between baseline and follow-up surveys).

In addition, a propensity score analysis was also performed. The propensity score was assessed from the logistic model estimating the probability of being assigned to a specific study arm given a set of known covariates. Students in the experimental arm were then matched without replacement to controls when their predicted propensity scores were the closest (nearest neighbour) (Rosenbaum and Rubin, 1983). The covariates used for the propensity-matching analysis were independent from the intervention, and included individual characteristics (age, gender, parents' education and origin), school type, and smoking status at baseline. These covariates were selected in order to produce two groups with comparable baseline information after matching. The effect of the intervention was then estimated by fitting a logistic model applied to the propensity score-matched database by allowing for intra-school correlation and including the unbalanced intervention-dependent variables (date of the baseline survey and days between baseline and follow-up surveys) as covariates (Joffe et al., 2004).

Analysis was done by intention to treat, with missing values on the outcome variable replaced by a value indicating current smoking. The software STATA 11 was used for the analyses.

Process evaluation

Classes' compliance to the whole programme and fidelity implementation of the school components were observed and documented for experimental schools.

This study is registered, number ISRCTN 10561880.

Results

Fig. 1 shows the trial profile. Thirteen schools participated to the study, 11 high schools and 2 vocational secondary schools. Overall, 77 classes out of 84 eligible classes of the target grade (91.7%), participated in the baseline survey with 1646 out of 2129 eligible students (77.3%), whereas 1282 students participated in the follow-up survey. Seventy-seven percent (989 / 1282) of follow-up questionnaires were matched to baseline ones: 61% of follow-up questionnaires identically reported the 9-digit codes of the baseline questionnaires, and 9% were retrieved through an iterative matching procedure (Galanti et al., 2007). The proportion of 77% of linked questionnaire was due to high turn-over of students from the first to second grade (failed students, students changed schools). Thus, overall participants under analysis were 989 students.

The proportion of respondents in the baseline and follow-up surveys were higher in high schools than in vocational secondary schools in the baseline survey (90.8% vs. 59.2%, respectively; $p < 0.001$). Moreover, in vocational schools the proportion of baseline questionnaires that matched with those of follow-up was significantly lower than in high schools (57.7% vs. 73.2% respectively, $p < 0.001$), due to a higher proportion of days of school absence among students attending vocational secondary schools.

Socio-demographic characteristics that showed a different distribution between intervention and control arms at baseline were gender,

Table 1
Baseline characteristics in respondents to baseline and follow-up surveys by study arm.

	Control N = 501	Intervention N = 488	p-Value	p-Value after adjustment
Age (%)				
<15 years	88.6	87.9	0.728	0.990
Gender (%)				
Girls	52.1	35.9	0.000	0.544
Boys	47.9	63.9		
Parents' education (%)				
Both parents with primary or middle school diploma	77.6	78.7	0.924	1.000
At least one parent with high school diploma or university degree	20.0	19.1		
Parents' origin (%)				
At least one parent born in Italy	89.2	88.5	0.911	1.000
Both parents born abroad	9.8	10.2		
School type (%)				
Vocational secondary school	12.2	5.1	0.000	0.249
High school	87.8	94.9		
Smoking outcomes (%)				
Cigarette use (past 30 days)	21.4	17.2	0.256	0.961
≥20 days of cigarette smoking in past 30 days	5.2	2.7	0.125	0.337
Lifetime cigarette use	28.9	24.4	0.105	0.603
Lifetime use of ≥100 cigarettes	6.2	3.9	0.100	0.692

as a lower proportion of girls was enrolled in the intervention arm, and type of school, as a lower proportion of students of vocational secondary schools was enrolled in the intervention arm (Table 1). Matching on propensity score produced two groups with comparable baseline information (Table 1). Moreover, in experimental schools the baseline survey was conducted 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 and 96.5% of enrolled students completed the peer-led intervention, 94.5% students participated in the SPP workshop, and 78.9% participated in the class lesson on one SPP workshop. All experimental schools formed a working-group on the school anti-smoking policy, verified the presence of no-smoking signs, and enforced and revised the school anti-smoking regulation, even though only 2 schools have actually implemented the revised regulation during the study period (Table 2).

Daily smokers at baseline (≥20 days of cigarette smoking in past 30 days) were 2.7% and 5.2% in the intervention and control arms, respectively, whereas at follow-up they were 10.9% and 15.8%, respectively (Table 3, Fig. 2).

Table 4 shows the estimates of the effect of the LdP programme. Multilevel regression and propensity score methods showed similar results. Students in the intervention arm showed a 31% lower prevalence of past 30-day smoking at the follow-up survey (OR matched on propensity score = 0.69; 95% CI: 0.50–0.95), and a 46% lower prevalence of daily cigarette use (OR matched on propensity score = 0.54; 95% CI: 0.40–0.72), compared to controls. The prevalence of frequent cigarette use (1–19 smoking days) did not differ between the two conditions (OR matched on propensity score = 0.85; 95% CI: 0.63–1.14). In non-smoking students at baseline, the OR matched on propensity score was 0.67 (95% CI: 0.42–1.06) for reporting 30-day smoking, and 0.41 (95% CI: 0.24,0.69) for reporting daily smoking (Tables 3, 4, Fig. 2). Students in the intervention arm that were non-smokers at baseline showed a non-significant 51% increase in reporting to be non-smokers at the follow-up survey compared to controls (OR matched on propensity score = 1.49; 95% CI: 0.94–2.36).

Moreover, the prevalence of 30-day smoking and frequent smoking in school areas (school playgrounds, corridors, toilets) was 62% and 78% lower, respectively, in the intervention arm compared to the control arm. (OR matched on propensity score = 0.38;95% CI: 0.16–0.90 for 30-day smokers, and OR = 0.22; 95% CI: 0.07–0.71 for frequent smokers) (Table 5).

Finally, we redid the analysis, now including the 7 schools that had violated the protocol. Results did not change substantially from those already reported (data not shown).

Discussion

Our study has shown that the LdP programme was successful in limiting the increase in the prevalence of past 30-day smokers at follow-up and, in particular, in limiting the increase in the prevalence of daily smokers (≥20 days of smoking in the past 30 days). Similar results were observed restricting the analyses to those reporting to be non-smokers at baseline. Additionally, exposure to the LdP programme was associated with a significantly lower prevalence of past 30-day smokers who reported to smoke in school areas.

LdP programme is a combination of different components: a peer-led intervention based on life skills, an extracurricular SPP workshop, a class

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

Programme components	Schools (%)	Students (%)
Peer education	6 (100.0)	471 (96.5)
SPP[a] workshop	6 (100.0)	461 (94.5)
Class lesson on one SPP workshop	4 (66.7)	385 (78.9)
At least one training lesson on SPP workshops for teachers	6 (100.0)	–
STP[b]: control of smoking signs and enforcement surveillance of the school policy; formation of a school working-group; revision of school smoking regulation	6 (100.0)	488 (100.0)
STP: introduction of the revised smoking policy during the study period	2 (33.3)	184 (37.7)

[a] SPP: Smoking Prevention Path.
[b] STP: School tobacco policies.

Table 3
Prevalence of smoking (%) and the corresponding 95% confidence interval (CI) at baseline and at eighteen months follow-up in the two study arms for all students, and for students that were non-smokers at baseline.

All students	Baseline	Follow-up		
	Control % (95% CI)	Intervention % (95% CI)	Control % (95% CI)	Intervention % (95% CI)
Past 30-day smoking (1+)	21.4 (17.8,25.0)	17.2 (13.9, 20.5)	33.7 (29.6, 37.9)	30.1 (26.1, 34.2)
Daily smoking (20+)	5.2 (3.3,7.1)	2.7 (1.3, 4.1)	15.8 (12.6, 19.0)	10.9 (8.1, 13.6)
Frequent smoking	16.2 (13.0,19.4)	14.5 (11.4, 17.6)	18.4 (15.0, 21.8)	19.3 (5.8, 22.8)
Non-smoking at baseline				
Past 30-day smoking (1+)	0.0	0.0	21.4 (25.5, 17.4)	19.9 (16.0, 23.7)
Daily smoking (20+)	0.0	0.0	6.6 (9.1, 4.2)	3.7 (1.9, 5.6)
Frequent smoking	0.0	0.0	14.8 (18.3, 11.3)	16.1 (12.5, 19.7)

lesson on one SPP topic to deliver life skills and knowledge on the harmful effects of smoking, and the enforcement of a STP. It was partially inspired to a recently evaluated school-based intervention (*Unplugged*), based on mixed social influence and social competence model (Faggiano et al., 2008), and on an informal school-based peer-led intervention (*ASSIST*) evaluated in UK (Campbell et al., 2008). The STP component enforced in the LdP programme was not inspired on specific interventions, since no rigorous evaluation studies were conducted so far (Galanti et al., in press), but its theoretical support appears strong: recent reports highlighted that adolescents who perceived school anti-smoking policies as strictly enforced also believed that tobacco was less available, more risky, less socially attractive, less used by their friends, and less acceptable (Lipperman-Kreda and Grube, 2009). These beliefs have been directly related to adolescents' past 30-day cigarette smoking (Lipperman-Kreda and Grube, 2009).

Although the main programme components are inspired to successful programmes, it is virtually impossible to disentangle the relative effects of every single component. This is a common problem of the prevention field (Hansen et al., 2007), for which some proposals has been addressed (Campbell et al., 2000; Collins et al., 2009), but never practiced. The possibility to unravel the role of each component could allow for programme improvements acting on the less effective components.

As a field trial, the study shares some limitations. First, 7 schools violated the protocol and 5 schools already participated in similar smoking prevention programmes. Thus, we excluded these 12 schools from the analyses, with a consequent reduction in the number of schools represented in the analyses (52%; 13 out of 25 secondary schools located in Reggio Emilia province). Nevertheless, the 7 non-compliant schools did, in fact, participate in the study even though they were not included in the analyses. Hence the total number of schools participating in the study was 20 out 25 secondary schools in Reggio Emilia (80%). We conducted a comparison of the baseline characteristics between the samples with and without the 7 non-compliant schools. There were no differences between these two samples, except for the distribution of gender (fewer girls in the intervention group in the sample without the 7 schools). Moreover, in an additional analysis (data not shown) main results did not differ significantly including the 7 non-compliant schools. So, in spite of the lower study coverage due to the 7 non-compliant schools, the risk of selection bias was low and study results can be generalized to other Italian secondary schools. In addition, the monitoring process showed that the intervention was completed by most experimental classes, demonstrating its practicability, in spite of its complexity.

Second, only 77% of questionnaires linked with those of the baseline survey: because of high turn-over in the first classes of secondary schools in Italy (due to failures, and changes of schools or classes by students), several adolescents recruited at the baseline survey were not present in the same classes 18 months later. Anyway, an attrition of 23% is not far from the average showed by other studies (Thomas and Perera, 2006). However, there were no differences in participation rates between experimental and control classes (Bosi et al., 2013). Third, the matching between baseline and follow-up questionnaires was significantly lower in vocational secondary schools. In our opinion this cannot reflect a higher risk of bias, but instead a real problem in the Italian school system. The implementation of the study in two waves, in order to ensure a higher surveillance on the study conduction, does not seem to have played a significant role in biasing results (data not shown). Moreover, the different distribution by study arm for gender, type of school, and time of baseline and follow-up surveys could have affected the results. In order to control for that, we carried out both a standard multilevel regression adjusted for these variables and

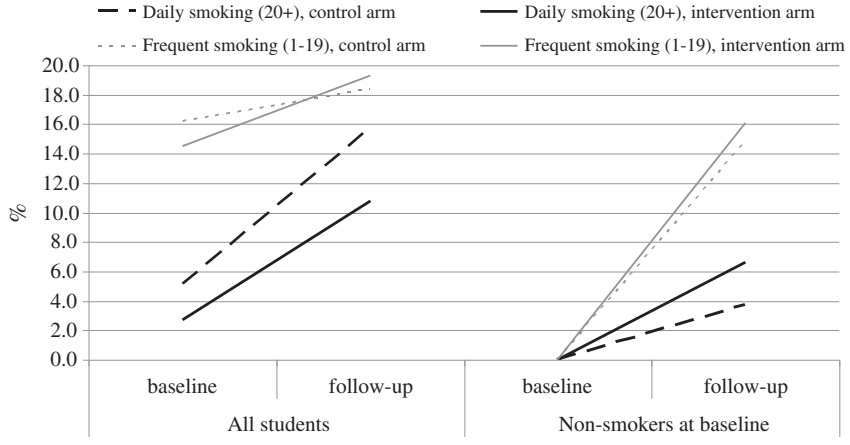

Fig. 2. Proportion of all students, and of non-smokers at baseline reporting past-30-day frequent (1–9) and daily (20+) smoking by study arm and survey (baseline, follow-up), with or without the 3 pairs of schools for change in the protocol.

Table 4
Effects of LdP programme at 18-months follow-up: odds ratios (OR) of smoking in past 30-day and 95% confidence intervals (CI).

All students			Multilevel logistic regression		Matched on propensity score
	Control	Intervention	Unadjusted	Adjusted	
	N = 501 7 schools	N = 488 6 schools	OR (95% CI)	OR (95% CI)[a]	OR (95% CI)
Past 30-day smoking (1+) at follow-up	169	147	0.84 (0.60, 1.17)	0.73 (0.41, 1.29)	0.69 (0.50–0.95)
Daily smoking (20+) at follow-up	79	53	0.65 (0.45, 0.94)	0.63 (0.35, 1.12)	0.54 (0.40–0.72)
Frequent smoking (1–19) at follow-up	90	94	1.01(0.73, 1.40)	0.96 (0.57, 1.62)	0.85 (0.63–1.14)
Non-smoking at baseline	N = 392	N = 403			
Past 30-day smoking (1+) at follow-up	84	80	0.89 (0.56, 1.42)	0.69 (0.41, 1.17)	0.67 (0.42–1.06)
Daily smoking (20+) at follow-up	26	15	0.53 (0.25, 1.14)	0.40 (0.17, 0.92)	0.41 (0.24–0.69)
Frequent smoking (1–19) at follow-up	58	65	1.05 (0.63, 1.77)	0.90 (0.53, 1.51)	0.79 (0.49–1.28)
Non-smoking at follow-up	308	323	1.12 (0.70, 1.78)	1.44 (0.86, 2.42)	1.49 (0.94–2.36)

[a] Adjusted for gender, type of school, past-30-day smoking at baseline, date of the baseline survey, and days between baseline and follow-up surveys.

Table 5
Effects of LdP programme at 18 months follow-up: odds ratios (OR) and 95% confidence intervals (CI) of reporting smoking in school areas (school playgrounds, corridors, toilets) for past 30-day smokers.

			Multilevel logistic regression		Matched on propensity score
	Control	Intervention	Unadjusted	Adjusted	
	N = 501 7 schools	N = 488 6 schools	OR (95% CI)	OR (95% CI)[a]	OR (95% CI)
Past 30-day smoking (1+) at follow-up	169	147	0.54 (0.31–0.92)	0.32 (0.13–0.80)	0.38 (0.16–0.90)
Daily smoking (20+) at follow-up	79	53	0.83 (0.21–3.22)	–	1.01 (0.20–4.87)
Frequent smoking (1–19) at follow-up	90	94	0.53 (0.21–1.35)	0.19 (0.06–0.60)	0.22 (0.07–0.71)

[a] Adjusted for gender, type of school, date of the baseline survey, and days between baseline and follow-up surveys, surveys, reporting smoking in school areas at baseline.

a propensity score-matching analysis. Stratifying results by gender, the effect of the programme was particularly evident for girls (OR for daily smokers = 0. 44,95% CI: 0.26–0.75), whereas for boys the adjusted OR was 0.62 (95%: 0.42–0.92). Thus, the differences in gender distribution by study arm (fewer girls in the intervention arm compared to controls) may have determined an underestimate of the effect of the intervention. On the contrary, the OR for daily smoking in high schools (OR = 0.51,95% CI: 0.41–0.62) did not differ significantly from the OR recorded considering also the vocational schools. So, the differences by type of school (fewer vocational students in the intervention arm) should not have affected the results significantly. A further limitation is the follow-up length: the complexity of the intervention, together with the evaluation study, prevented for the possibility to conduct a longer follow-up, limiting the results to 8 months after baseline, i,e. 6 months after the completion of the intervention. This limit is shared by many trials in the field of smoking prevention (Thomas and Perera, 2006).

In conclusion the LdP programme appears to be effective in preventing students from becoming daily smokers, and in preventing students from smoking in school areas six months after the end of the active intervention phase. This seems a good news: smoking is accounting for about 71,000 attributable deaths in Italy in 2010 (Gallus et al., 2010), and virtually all Italian schools, even if not every year, provide programmes against smoking. But in a recent survey, less than 1% of those interventions have been ever evaluated (Coffano, 2009). Providing to practitioners and policy-makers new effective programmes is of crucial relevance in order to ensure public health impact of smoking prevention.

Competing interests

The authors have no potential conflict of interest.

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Appendix A

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/topic	Item no	Checklist item	Reported on page no
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4, 5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	–
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	–
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	–
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	–
	11b	If relevant, description of the similarity of interventions	–
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	6, 7
	13b	For each group, losses and exclusions after randomisation, together with reasons	6, 7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	–
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Fig. 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	5, 6, Tables 2 and 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	–
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	6, 7
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	–
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	9
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	–
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8, 9
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	4, references
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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