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A prevention program for multiple health-compromising behaviors in adolescence: Baseline results from a cluster randomized controlled trial ☆

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ABSTRACT

Objective. To describe the design and present the baseline findings of the evaluation study of 'Paesaggi di Prevenzione', a school-based prevention program tackling smoking, alcohol misuse, dietary risks, and physical inactivity in 12- to 14-year-olds.

Methods. The program was implemented from January 2011 to April 2012 in Emilia-Romagna, Italy, and comprised classroom activities and school-wide policies. A two-arm cluster randomized controlled trial was designed. Schools were the units of randomization and were matched by socioeconomic status, size, and type.

Results. Data from 4700 middle school students and 2952 high school students were collected anonymously from October to December 2010. Past-30-day smoking prevalence was 1.9% among middle school students and 20.8% among high school students. Past-30-day prevalence of alcohol intoxication was 2.2% among middle school students and 11.4% among high school students. A total of 39.7% of middle school students and 48.0% of high school students drank sugar-sweetened beverages four or more times per week; 7.5% of middle school students and 7.1% of high school students had intense physical activity every day.

Conclusions. This study seems adequately powered and baseline variables appear evenly distributed between study groups. Findings are in line with those of the WHO Health Behaviour in School-Aged Children study.

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Background

Seven risk factors account for 56.1% of the attributable disability-adjusted life year (DALYs) in Western Europe: dietary risks, smoking, high blood pressure, high body mass index, physical inactivity, excessive alcohol consumption, and high fasting plasma glucose (Institute for Health Metrics and Evaluation, 2013).

In 2006, the WHO Regional Office for Europe started 'Gaining Health' (WHO Europe and WHO Regional Office for Europe, 2006), a policy framework aiming to contrast the main risk factors and socioeconomic determinants of non-communicable diseases in Europe. A political response followed in Italy (DPCM 4 Maggio, 2007) to encourage the dissemination of prevention programs tackling health-compromising behaviors, with particular focus on smoking, alcohol misuse, dietary risks, and physical inactivity.

Schools are considered some of the most appropriate places for the implementation of prevention programs (Centers for Disease Control and Prevention, 1994). Students attend school during their adolescence years, when some patterns of health-compromising behaviors may start to appear, and teachers are often willing to convey prevention messages. Evidence supports the effectiveness of some school-based interventions tackling alcohol misuse (Foxcroft and Tsertsvadze, 2011, 2012), dietary risks (Kremers et al., 2007), and sedentary behavior (Kremers et al., 2007; Van Sluijs et al., 2007). There is mixed evidence on the effectiveness of school-based smoking prevention interventions (Thomas and Perera, 2006), although a recent study provided promising results (Gorini et al., 2014).

Research shows that some risk behaviors, such as alcohol misuse, tobacco smoking, physical inactivity, and antisocial behavior cluster in adolescence, both at a group level and at an individual level (Basen-Engquist et al., 1996; DuRant et al., 1999; Farhat et al., 2010;

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MacArthur et al., 2012; WHO Europe and WHO Regional Office for Europe, 2006) and that such behaviors are associated with increased and cumulative risk of poor educational attainment, morbidity and premature mortality (Khaw et al., 2008; Kvaavik et al., 2010).

Although some programs have targeted multiple risk behaviors simultaneously (Faggiano et al., 2008; Noar and Zimmerman, 2005), to our knowledge no evidence is available on universal interventions tackling simultaneously the four health-compromising behaviors which are the principal target of the 'Gaining Health' strategy in Italy.

The Regional Authority of Emilia-Romagna, an administrative area in Northern Italy (population in 2012: 4.3 million (Italian National Institute of Statistics (ISTAT), 2013)), is deeply engaged in the contrast of risk behaviors. Current public health activities encompass the implementation of public health policies, such as a smoking ban at schools and healthcare facilities, and the development of school-based prevention programs, such as a successful program tackling smoking initiation in adolescence—the Luoghi di Prevenzione-Prevention Grounds program (LILT-LdP) (Bosi et al., 2013; Gorini et al., 2014).

This paper aims to describe the design and present the baseline findings of the evaluation study of 'Paesaggi di Prevenzione', a prevention program developed by the Emilia Romagna Regional Authority on top of the LILT-LdP experience and tackling simultaneously smoking, alcohol misuse, dietary risks, and physical inactivity.

Methods

The 'Paesaggi di Prevenzione' program

'Paesaggi di Prevenzione' is a multi-target prevention program aimed at developing healthy lifestyles in 12 to 14 years old students (Bertini et al., 2006; Botvin et al., 1995). The program aims to reduce initiation to tobacco smoking and alcohol misuse, to improve the quality of diet, and to increase frequency and intensity of physical activity. It was developed in two versions, one for middle school students (12 year olds) and one for high school students (14 year olds).

'Paesaggi di Prevenzione' is based on two components: (i) an interactive classroom curriculum delivered by trained teachers with the support of audio-visual media and (ii) school policies developed by students, teachers, and families, and approved by the school authorities. Each component has specific manuals and materials available on the program website (www.luoghidiprevenzione.it/PaesaggiDiPrevenzione/default.aspx).

The classroom component comprises four independent pathways, one for each behavior targeted by the program. Teachers can choose the pathways to implement, tailoring the program to the specific needs of their students. Interactive classroom activities are intended to enhance decision making skills, problem solving, personal and interpersonal skills, management of stress and emotions, and effective communication. In this evaluation study, teachers ($n = 271$) were trained over three 4-hour sessions delivered by a group ($n = 80$) of public health professionals and lead teachers, whom were previously trained over two 8-hour sessions administered centrally at the Health Promotion centre of the Italian League against Cancer (LILT) in Reggio Emilia, Italy.

School policies comprise smoking bans for both student and teachers inside and outside school facilities, prohibition to use alcohol during school events, promotion of use of healthy foods in selling machines and canteens, walking activities involving families and local communities, and team games.

Study design

A two-arm cluster randomized controlled trial was designed. The experimental group implemented 'Paesaggi di Prevenzione' from January 2011 to April 2012, and the control group was administered the usual school curriculum. Students from both study arms filled out a baseline survey from October to December 2010 and a post-intervention survey in May 2012. High school students were also administered a follow-up survey in May 2013, while middle school students could not as their standard course of study lasts three years in Italy.

Units of analysis

Students were the units of analysis. Schools were the unit of randomization.

Sample size

The sample size was estimated conservatively on the basis of the targeted behavior with the lowest anticipated prevalence at baseline, i.e., tobacco smoking. An overall sample size of 5200 middle school students and 3400 high school students was calculated assuming 5% type I error ($z_{\alpha/2}$), 80% power (z_{β}), and a different past-30-day smoking prevalence in the intervention and control groups. The anticipated smoking prevalence in the control group (P_2) was obtained from 2009 to 2010 age-specific regional figures of the WHO Health Behaviour in School-aged Children (HBSC) study for Emilia Romagna (Angelini et al., 2010). Smoking prevalence in the experimental group (P_1) was calculated assuming a 30% reduction in P_2 in the experimental group, in line with the three-month findings of another prevention program tackling smoking and other risk behaviors (Faggiano et al., 2008). For middle schools, P_1 was 7% and P_2 was 10%. For high schools, P_1 was 11% and P_2 was 15%. An inflation factor (IF) of 1.9 was obtained via the formula $1 + (m - 1) \times \mathrm{ICC}$, in which m is the average size of the cluster, assumed to be 25 students per class, and ICC is the intraclass correlation coefficient for past-30-day smoking, which was assumed to be 0.039 consistently with a previous study (Faggiano et al., 2007). The IF was applied to calculations of sample sizes for both middle schools and high schools.

$$\text{Sample size} = 2 \times \frac{\left(z_{\alpha/2} + z_{\beta}\right)^2 [P_1(1-P_1) + P_2(1-P_2)] \times IF}{(P_1 - P_2)^2}$$

The assumed ICC of 0.039 was compared with the ICC estimated from our baseline data (McGraw and Wong, 1996; Shrout and Fleiss, 1979).

Eligibility of schools

All urban state schools with four or more sections were candidate to enrolment. Middle schools were selected in 10 out of 11 Local Health Authorities of the Emilia-Romagna administrative area: Piacenza, Parma, Reggio Emilia, Bologna, Imola, Ravenna, Cesena, Rimini, Ferrara, and Modena. High schools were selected from all of the above with the exception of the Authority of Reggio Emilia, which was already participating to another trial (Bosi et al., 2013; Gorini et al., 2014).

Eligibility of students

All students attending the participating schools were included in the survey, with the exception of those who were unable to participate in the survey due to general learning disability.

Randomization and allocation concealment

Schools were stratified by socioeconomic status, size, and type (i.e., middle schools and high schools) to form strata of schools presenting similar characteristics. High schools were also stratified by subtype, i.e., vocational or preparatory. Within each stratum, schools were randomly assigned to the experimental or control arm using a computer-generated list of random numbers. The allocation procedure was carried out centrally by independent contractors, Avogadro University and the Cancer Prevention and Research Institute (ISPO), which did not know the schools nor lived in the administrative area where the program was implemented.

Outcome measures

We obtained student-level information on self-reported behavioral outcomes, possible mediators, and sociodemographic characteristics. Students from both study arms filled out an anonymous baseline survey from October to December 2010 and an anonymous post-intervention survey in May 2012. High school students were also administered an anonymous follow-up survey in May 2013, while middle school students could not as their standard course of study lasts three years in Italy.

Behavioral outcome variables were selected among those commonly used in the literature (Angelini et al., 2010; Currie et al., 2008; Faggiano et al., 2007;

Sloboda et al., 2009). Students were asked about the number of days per month they smoked cigarettes or experienced alcohol intoxication.

Due to the multifaceted effects of eating behaviors on health, it is difficult to distinguish between healthy and unhealthy eating behaviors. Students were asked how many days per week they used to eat fruit, vegetables, snacks, crisps, cakes and ice creams, fish, legumes, milk or yogurt, meat, or dairy products; had breakfast; and used to drink sugar-sweetened beverages. Due to the need to come up with a reasonable number of indicators and thus avoid potential inflating of type I errors (Benjamini and Hochberg, 1995), and consistently with the Italian Dietary Guideline (National Institute of Research for Food and Nutrition (INRAN), 2003) and with previous works (Perry et al., 1998, 2004), we hypothesized that 'Paesaggi di prevenzione' would have reduced some particular behaviors (such as drinking sugar-sweetened beverages; eating crisps and snacks; eating cakes and ice creams), while encouraging others (e.g., eating fruit and vegetables; having regular breakfast every day). In this paper, we have therefore focused on such behaviors.

Students were also asked how many days per week and how many hours per day they did moderate or vigorous physical activity, as defined in the HBSC study and consistently with previous work (Bayne-Smith et al., 2004; Robbins et al., 2006): 'any activity that increases your heart rate and makes you get out of breath some of the time for at least 60 minutes', and how many hours per day they watched TV and used computers or videogames (Currie et al., 2008) and consistently with. A copy of the questionnaire in Italian can be requested from the authors.

Based on the assumed theoretical model, the main mediators of behavioral effect were also measured to allow exploring of possible mediation effects.

Variations from study protocol

Just after the randomization procedure and before the start of the program, three control schools implementing other prevention activities were switched to the intervention group. Such schools ($n = 3$) and their matched counterparts ($n = 3$) were therefore excluded from the analyses.

In one stratum both schools were implementing other prevention interventions and their allocation was not changed because they appeared to be balanced with regard to the amount, quality and intensity of the ongoing interventions. Such pair of school was kept in the analyses.

Dropouts

Schools

Three middle schools and three high schools allocated to the intervention group opted out just after randomization as their teachers were already committed to other activities. This resulted in exclusion of their matched control schools. Due to the *exitus* of the teacher appointed to leading the implementation of the program, one middle school dropped out after the baseline survey was administered. This school and its control were excluded from analyses.

Classes

One middle-school class in the control arm and one high-school class in the intervention arm dropped out after randomization and before the administration of the baseline survey due to other commitments of the teachers.

Statistical methods

We carried out a descriptive analysis of the baseline characteristics by study arm. Chi-squared tests were performed to test differences in prevalence of categorical variables. *T*-tests were used to test differences in mean of continuous variables. We conducted separate analyses for middle schools and for high schools.

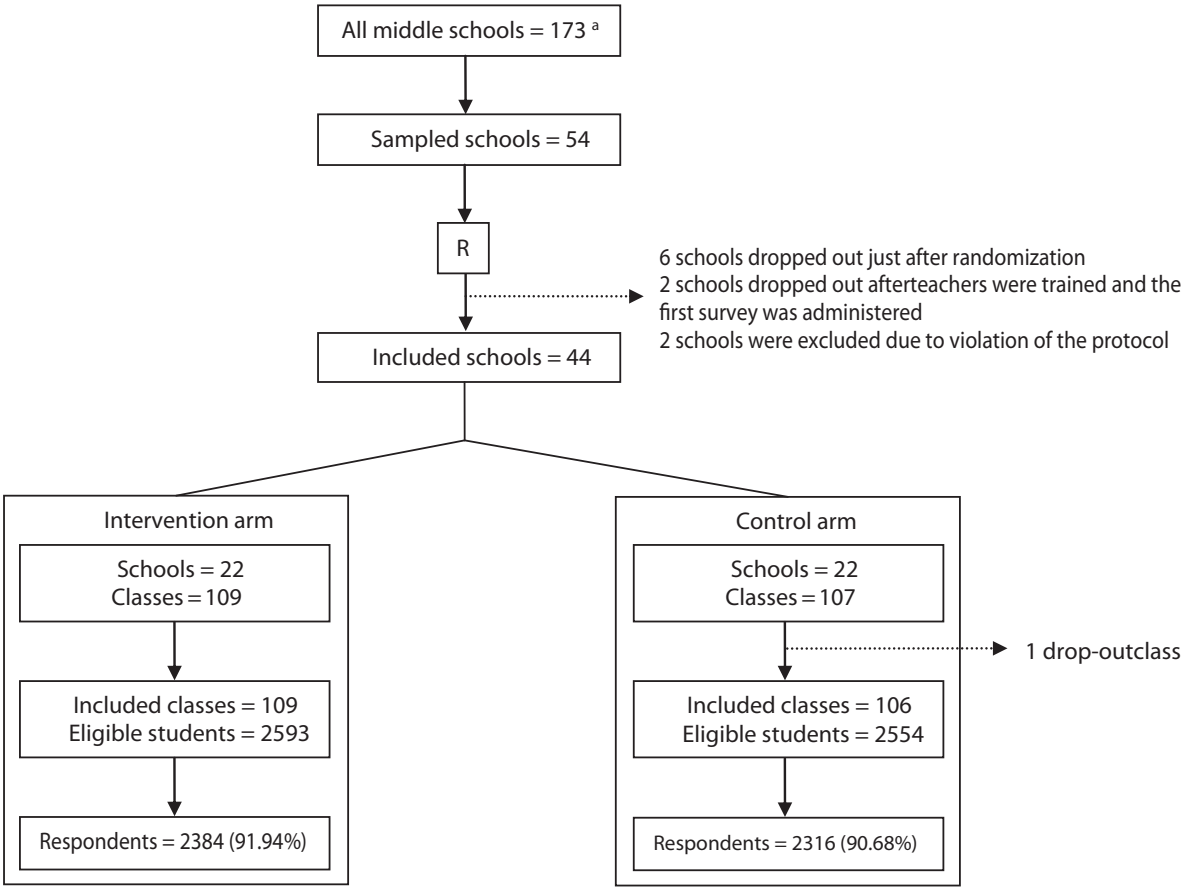


Fig. 1. Enrolment of middle school students. [a] All middle schools in the 10 Local Health Authorities of Piacenza, Parma, Reggio Emilia, Bologna, Imola, Ravenna, Cesena, Rimini, Ferrara, and Modena.

Ethics

The study was registered on www.controlled-trials.com with number ISRCTN00953701 and was approved by the Ethics Committee of the Local Health Authority of Reggio Emilia, Italy, with resolution number 0033/DS. A copy of the protocol can be requested from the authors. Parents and carers were informed of the 'Paesaggi di Prevenzione' trial, and students had the option to opt out at any moment. All data were collected anonymously. In order to link the baseline questionnaire with the post-intervention questionnaire, we used a 9-digit unique code generated by the students, which was already used successfully in other trials (Faggiano et al., 2008; Galanti et al., 2007; Gorini et al., 2014).

Results

Enrolment and respondents

At the end of the enrolment process, 54 middle schools were sampled and 44 could be included (Fig. 1). 4700 out of 5147 eligible middle school students (91.3%) filled out the baseline questionnaire.

Forty-four high schools were sampled, and 34 could be included (Fig. 2). Of 3349 eligible high school students, 2952 (88.2%) filled out the baseline questionnaire.

Characteristics of the enrolled population

Middle schools

Mean age in the sample of middle schools was 12.1 years old (standard deviation [SD] 0.45) (Table 1). Around 49.1% were girls. Nearly 85.4% of the students came from families with medium or high socioeconomic status (SES). About 85.2% of the students in the intervention group and 82.2% of the students in the control group ($p = 0.005$) had at least one parent of Italian descent.

High schools

Mean age was 14.3 years old (SD 0.68). Nearly 47.4% of the students in the intervention group and 41.8% of the students in the control group were girls ($p = 0.003$). Nearly 82.4% of the students came from families with medium or high SES. Almost 85.1% had at least one parent of Italian descent.

Tobacco smoking

Middle schools

Around 1.9% of the students smoked at least once in the past 30 days, and 0.5% smoked at least 20 times (Table 2).

High schools

Approximately 20.8% of the students smoked at least once in the past 30 days, with some evidence of a greater prevalence ($p = 0.046$) in the intervention group (22.5%) compared to the control group (19.4%). 8.8% of the students smoked at least 20 times in the previous month.

Alcohol misuse

Middle schools

Prevalence of past-month alcohol intoxication was 2.2% (Table 2). There was some evidence ($p = 0.050$) of greater prevalence of post-month frequent (three or more) episodes of intoxication among students in the control arm (1.1%) compared to students in the intervention arm (0.6%).

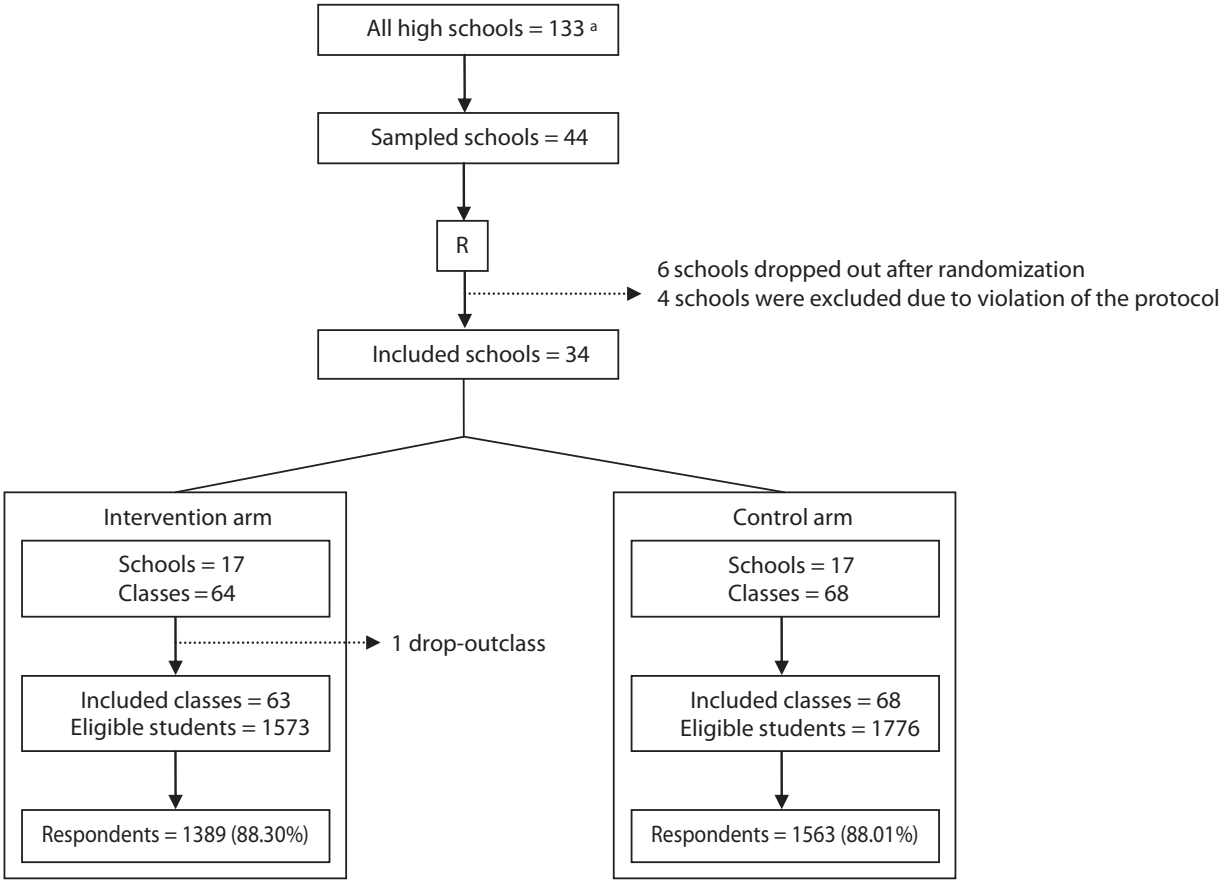


Fig. 2. Enrolment of high school students. [a] All high schools in the 9 Local Health Authorities of Piacenza, Parma, Bologna, Imola, Ravenna, Cesena, Rimini, Ferrara, and Modena.

Table 1
Baseline sociodemographic characteristics in recruited students by study arm.

	Middle schools				High schools			
	Intervention ($n = 2384$)	Control ($n = 2316$)	Total ($N = 4700$)	p-value[a]	Intervention ($n = 1389$)	Control ($n = 1563$)	Total ($N = 2952$)	p-value[a]
Age in years (mean (SD))	12.08 (0.41)	12.10 (0.49)	12.09 (0.45)	0.127	14.30 (0.68)	14.31 (0.68)	14.31 (0.68)	0.539
Sex (n (%))								
Females	1171 (49.79)	1101 (48.46)	2272 (49.13)	0.367	**652 (47.35)**	**642 (41.80)**	**1294 (44.42)**	**0.003**
Males	1181 (50.21)	1171 (51.54)	2352 (50.87)		**725 (52.65)**	**894 (58.20)**	**1619 (55.58)**	
Socioeconomic status[b] (n (%))								
Low	335 (14.96)	305 (14.17)	640 (14.58)	0.166	253 (18.97)	248 (16.46)	501 (17.63)	0.210
Medium	1016 (45.38)	933 (43.36)	1949 (44.39)		669 (50.15)	773 (51.29)	1442 (50.76)	
High	888 (39.66)	914 (42.47)	1802 (41.04)		412 (30.88)	486 (32.25)	898 (31.61)	
Origin (n (%))								
A least one parent is Italian	**2026 (85.20)**	**1898 (82.20)**	**3924 (83.72)**	**0.005**	1173 (84.88)	1326 (85.22)	2499 (85.06)	0.796
Both parents are non-Italian	**352 (14.80)**	**411 (17.80)**	**763 (16.28)**		209 (15.12)	230 (14.78)	439 (14.94)	

Note: in bold are the characteristics for which there is evidence at the 5% level of a difference between intervention and control group.
[a] Comparisons between study groups. *T*-test for age; chi-squared tests for other variables.
[b] Low = both parents or guardians have a middle school or elementary qualification. Medium = at least one parent or guardian has a high school qualification; the other may have a lower qualification. High = at least one parent or guardian has a university degree; the other may have a lower qualification.

High schools

Prevalence of past-month alcohol intoxication was 11.4%. Past-month frequent intoxication was observed in 4.1% of the students.

Eating behavior

Middle schools

Approximately four students out of ten used to eat fruit every day (Table 3), and one third used to eat vegetables every day. More than 70% had breakfast every day. With regards to unhealthy behaviors, 39.7% used to drink sugar-sweetened beverages, 34.5% used to eat crisps and snacks, and 37.7% used to eat cakes and ice creams four or more times per week. The mean score of eating behavior was 3.6 (SD 1.41), i.e., in the upper half of the range.

High schools

Approximately one third of the students used to eat fruit and to eat vegetables every day. Nearly sixty-percent had breakfast every day. 48.0% used to drink sugar-sweetened beverages, 39.1% used to eat crisps and snacks, and 41.4% used to eat cakes and ice creams four or more times per week. The mean score of eating behavior was 3.2 (SD 1.43), i.e., in the lower half of the range.

Physical activity and sedentary behavior

Middle schools

Nearly 14.4% of the students had at least 60 minutes of physical activity and 7.5% had intense physical activity, defined as 'physical activity that makes you out of breath or warmer than usual', every day (Table 3). Nearly one third used to watch television three or more hours per day, and nearly twenty-nine percent used computers or videogames three or more hours per day.

High schools

Nearly 15.0% of the students had at least 60 minutes of physical activity and 7.1% had intense physical activity every day. More than one third of the students used to watch television three or more hours per day, and nearly forty-four percent used computers or videogames three or more hours per day.

Intracluster correlation

Intraclass correlation coefficients (ICCs) were calculated separately for middle schools and high schools, and for each of the 12 outcome variables presented in this paper (see Appendix 1 for further details). Of 24 ICCs, 19 were smaller or much smaller than 0.039, i.e., the ICC anticipated when we carried out sample size calculations. Four ICCs were slightly greater and were ranging from 0.040 to 0.052. One ICC was equal to 0.086 and referred to past-30-day smoking among high school students.

Discussion

To our knowledge, this is the first Italian study aiming to assess the effectiveness of a school-based prevention program simultaneously targeting smoking, alcohol misuse, eating behavior, and sedentary behavior. This study involved 7652 students and mobilized resources in one of the most populated administrative areas in Italy.

After exclusion of schools, which violated the protocol or opted out, the sample size for middle schools was around 90% of the anticipated sample size (4700/5200), and the sample size for high schools was approximately 87% of the anticipated sample size (2952/3400). Sample size calculations were conservative and based on the prevalence of tobacco smoking, which was the least prevalent behavior among

Table 2
Baseline prevalence of cigarette smoking and alcohol misuse in recruited students by study arm.

	Middle schools				High schools			
	Intervention ($n = 2384$)	Control ($n = 2316$)	Total ($N = 4700$)	p-value[a]	Intervention ($n = 1389$)	Control ($n = 1563$)	Total ($N = 2952$)	p-value[a]
Past-30-day tobacco smoking (%)								
Current smoker (1+ times)	41 (1.83)	44 (2.05)	85 (1.94)	0.606	**291 (22.47)**	**283 (19.38)**	**574 (20.83)**	**0.046**
Frequent smoker (20+)	8 (0.36)	12 (0.56)	20 (0.46)	0.324	105 (8.11)	136 (9.32)	241 (8.75)	0.263
Past-30-day alcohol misuse (%)								
Current alcohol intoxication (1+ times)	44 (1.97)	53 (2.48)	97 (2.22)	0.249	143 (11.05)	170 (11.77)	313 (11.43)	0.553
Frequent alcohol intoxication (3+ times)	**13 (0.58)**	**24 (1.13)**	**37 (0.85)**	**0.050**	54 (4.17)	57 (3.95)	111 (4.05)	0.765

Note: in bold are the behaviors for which there is evidence at the 5% level of a difference between intervention and control group.
[a] Pearson's chi-squared test.

Table 3
Baseline prevalence of eating behaviors, physical activity, and sedentary behavior in recruited students by study arm.

	Middle schools				High schools			
	Intervention ($n = 2384$)	Control ($n = 2316$)	Total ($N = 4700$)	p-value[a]	Intervention ($n = 1389$)	Control ($n = 1563$)	Total ($N = 2952$)	p-value[a]
Eating behaviors (n (%))								
Fruit consumption everyday	948 (40.22)	951 (41.56)	1899 (40.88)	0.352	474 (34.42)	490 (31.69)	964 (32.98)	0.117
Vegetables consumption everyday	820 (34.83)	803 (35.10)	1623 (34.96)	0.852	397 (28.94)	444 (28.85)	841 (28.89)	0.959
Breakfast everyday	1656 (69.99)	1617 (70.21)	3273 (70.06)	0.817	820 (59.21)	939 (60.35)	1759 (59.81)	0.529
Sugar-sweetened drinks 4+ times per week	930 (39.73)	904 (39.67)	1834 (39.70)	0.967	651 (47.80)	742 (48.18)	1393 (48.00)	0.836
Crisps and snacks 4+ times per week	803 (34.87)	762 (34.19)	1565 (34.53)	0.629	537 (39.63)	594 (38.67)	1131 (39.12)	0.598
Cakes and ice creams 4+ times per week	866 (37.06)	867 (38.30)	1733 (37.67)	0.386	586 (42.93)	614 (40.03)	1200 (41.39)	0.113
Physical activity (%)								
At least 60 minutes of physical activity per day	324 (14.07)	327 (14.68)	651 (14.37)	0.555	192 (14.13)	238 (15.70)	430 (14.96)	0.238
Intense physical activity per day	162 (6.92)	186 (8.18)	348 (7.54)	0.105	85 (6.19)	121 (7.92)	206 (7.10)	0.070
Sedentary behavior (%)								
Watches TV 3+ hours per day	759 (32.20)	743 (32.45)	1502 (32.32)	0.859	464 (33.77)	537 (34.80)	1001 (34.32)	0.558
Uses computer or videogames 3+ hours per day	662 (28.17)	676 (29.52)	1338 (28.84)	0.310	597 (43.26)	682 (43.94)	1279 (43.62)	0.710

[a] Pearson's chi-squared test.

those targeted by 'Paesaggi di Prevenzione'. Therefore, the sample size of this study appears to provide acceptable power for detecting changes in the risk behaviors addressed by the program.

In general, baseline and sociodemographic characteristics appear to be balanced between study groups. Some imbalance is noted for two variables (out of seventeen) for each type of schools. Differences in such variables appear small in size and their level of statistical significance might be due to the large sample size. Analyses accounting for the clustering due to individuals belonging to the same school might estimate larger standard errors, which would likely result in low or no evidence of a difference in baseline variables. Whenever needed, later analyses should however account for the potential confounding effects of baseline variables. Adjustment for potential confounders is common practice in cluster randomized controlled trials, in which allocation is not conducted at an individual level (see, for example, (Faggiano et al., 2008, 2010)).

The prevalence of behavioral outcomes are in line with the findings of the 2009–2010 Health Behaviour in School-aged Children (HBSC) survey (Angelini et al., 2010), with the exception of three indicators. Students enrolled in this study appeared to experiment alcohol intoxication less often and to practice physical activity more often than their HBSC counterparts, while eating less fruit.[1] A sample composed by healthier subjects could potentially hinder the ability to detect a behavioral change due to the 'Paesaggi di Prevenzione' program. However, the differences in prevalence of behavioral outcomes between this study and the HBSC study were small in most cases, and the conservative sample calculations we carried out are likely to provide sufficient power.

For most behaviors, intracluster correlation coefficients (ICCs) are lower or much lower than the ICC anticipated when carrying out sample size calculations. The estimated ICCs therefore seem unlikely to affect the ability of the study to detect changes in most of the behaviors targeted by 'Paesaggi di Prevenzione', although some caution might be needed in interpreting program effects on smoking behavior of high-school children. However, it is worth noting that another Italian study (Gorini et al., 2014), which based its sample size calculations on the same ICC anticipated in our study, found evidence of a program effect on past-30-day smoking behavior among high-school children. This may be partly due to the fact that smoking prevalence increases with age, thus requiring a smaller sample size to detect the same effect size. The anticipated sample size for high school children may therefore be sufficient for detecting a post-intervention change in smoking behavior due to 'Paesaggi di Prevenzione' among high-school children.

Currently, only a few school-based prevention programs were found effective after rigorous evaluation. This is partly due to the common perception that carrying out an accurate and adequately powered evaluation study may be impracticable without considerable funding. This misconception has a negative impact both on research, by hindering the advancement of prevention science, and on practice, by reducing the supply of effective prevention programs. This study may also serve to show that conducting a large randomized trial for the evaluation of a prevention program is feasible even without specific funding, provided that the local health authorities and their public health professionals are committed to the project.

In general, this paper shows that the sample size and the distributions of study variables may be appropriate for the evaluation of the 'Paesaggi di Prevenzione' program, provided that statistical analyses do not fail to account for possible confounding effects.

Competing interests
The authors declare that there are no conflicts of interest.

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List of abbreviations

DALY	disability-adjusted life year
WHO	World Health Organization
HBSC	Health Behaviour in School-Aged Children
SES	socioeconomic status
SD	standard deviation

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[1] Prevalence of alcohol misuse was lower in this study than in the HBSC study (5.0% among eleven years old, 8.4% among thirteen years old, and 25.0% among fifteen years old)(Angelini et al., 2010). Prevalence of daily physical activity for at least 60 minutes was considerably greater in this study among both middle and high school students than in the HBSC study (7.0% among eleven years old, 6.5 among thirteen years old, and 6.8 among fifteen years old). However, prevalence of daily fruit consumption was lower in this study than in the HBSC study (44.4% among eleven years old, 40.4% among thirteen years old, and 40.8% among fifteen years old).

the program, to the teachers involved in the program, and to the school authorities.

Appendix 1

Intracluster correlation coefficients (ICCs) estimated from baseline data for each outcome variable

Outcome variable	Middle schools ICC (95%CI)	High schools ICC (95%CI)
Substance use		
Past-30-day smoking	0.021 (0.011 to 0.041)	**0.086 (0.058 to 0.126)**
Past-30-day alcohol misuse	0.018 (0.009 to 0.037)	**0.045 (0.026 to 0.076)**
Eating behaviors		
Fruit consumption	0.007 (0.002 to 0.029)	0.022 (0.011 to 0.044)
Vegetables consumption	0.024 (0.014 to 0.042)	0.036 (0.021 to 0.060)
Breakfast	0.012 (0.005 to 0.030)	0.015 (0.006 to 0.037)
Sugar-sweetened drinks	0.026 (0.016 to 0.044)	0.037 (0.022 to 0.062)
Crisps	**0.040 (0.027 to 0.059)**	0.035 (0.021 to 0.060)
Cakes and ice creams	0.017 (0.008 to 0.034)	0.011 (0.003 to 0.034)
Physical activity		
Physical activity for at least one hour	0.013 (0.005 to 0.030)	0.031 (0.017 to 0.055)
Physical activity leading to being out of breath	0.007 (0.002 to 0.029)	0.032 (0.019 to 0.053)
Time spent watching TV	0.034 (0.022 to 0.052)	**0.052 (0.033 to 0.081)**
Time spent using a computer or videogames	0.031 (0.019 to 0.049)	**0.041 (0.024 to 0.068)**

Note: in bold are ICCs greater than the ICC of 0.039 anticipated when carrying out sample size calculations.

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