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

Elias Allara [a,b,*], Paola Angelini [c], Giuseppe Gorini [d], Sandra Bosi [e], Giulia Carreras [d], Cristina Gozzi [e], Andrea Martini [d], Marco Tamelli [e], Simone Storani [e], Fabrizio Faggiano [a]

[a] Department of Translational Medicine, Avogadro University, Novara, Italy
[b] School of Public Health, University of Torino, Torino, Italy
[c] Public Health Unit, Emilia-Romagna Regional Authority, Bologna, Italy
[d] Environmental and Occupational Epidemiology Unit, Cancer Prevention and Research Institute (ISPO), Florence, Italy
[e] Italian League against Cancer (LILT), Reggio Emilia, Italy

ARTICLE INFO

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.

© 2014 Elsevier Inc. All rights reserved.

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;

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 $1 + (m - 1) \times ICC$, 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;