ISRCTN00953701 https://doi.org/10.1186/ISRCTN00953701

Prevention Landscapes: a study for evaluating a school-based intervention for preventing smoking and alcohol consumption and for improving nutrition and physical activity in students aged 11 - 12 and 13 - 14 years in Emilia-Romagna Region, Italy

Submission date 30/08/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/03/2011	**Overall study status** Completed	
Last Edited 15/04/2019	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Paola Angelini

Contact details
Public Health Unit
Emilia-Romagna Region
V.le A. Moro, 21
Bologna
Italy
40127
-
PAngelini@regione.emilia-romagna.it

Additional identifiers

Protocol serial number

Study information

Scientific Title
A cluster randomised controlled trial for evaluating a school-based prevention intervention on tobacco and alcohol consumption, nutrition and physical activity for students aged 11 - 12 and 13 - 14 years

Acronym
PdP Trial

Study objectives
To verify whether the comprehensive intervention carried out in the schools of the experimental arm (intervention schools) determines an increased number of students that improve their lifestyles (do not take up smoking; do not increase their alcohol consumption; improve nutrition, and physical activity) after one year after the intervention, in comparison to control schools.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Local Health Authority of Reggio Emilia, Italy approved on 20th Decenber 2010

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Lifestyle improvement

Interventions
From the list of all FLS and SLS in the 10 Emilia-Romagna areas, we excluded those that had already participated in prevention programmes in last years and we selected 173 FLS and 133 SLS with at least four 2nd classes and four 1st classes, respectively.

Moreover, we chose 54 FLS and 44 SLS with the highest number of classes and located in towns, in order to be more reachable by health professionals involved in the trial.

In order to recruit about 6,000 students attending the 1st class FLS, we need to involve at least five 2nd classes each school. In order to recruit about 4,500 students attending the 1st class FLS, we need to involve at least four 1st classes each school.

The participating 54 FLS and 44 SLS have been paired according to the number of attending students in the preceding school-year and for being located closely. In addition, the participating SLS have been paired according to the type of school (technical school; high school).

The pre-intervention surveys will be conducted in October-December 2010. In the experimental arm the intervention will be delivered during the period January-May 2010. The follow-up survey both in experimental and control schools will be carried out in October-December 2011.

The intervention in the experimental arm is characterised by:
1. The use of DVD "Prevention Landscapes" (DVD PdP; http://www.koalagames.eu/paesaggi/manuali.aspx) by both teachers and students. At least two teachers will be trained to use materials, tools, texts and slides to present selected subjects on the four lifestyles (tobacco, alcohol, nutrition, and physical activity). Students should use the DVD sections with games, cartoons and in-depth documents on the four selected lyfe-styles.
2. Enforcement of school policies on the four lifestyles:
2.1. Enforcement of a alcohol and tobacco school policy
2.2. Enforcement of a school policy to improve nutrition and physical activity

Intervention Type
Behavioural

Primary outcome(s)
1. Tobacco:
1.1. Lifetime cigarette use
1.2. Current cigarette use (past 30 days)
1.3. Frequent use of cigarettes (20 or more days of cigarette smoking in past 30 days)
Primary outcome measures will be adjusted for recorded confounders (smoking prevalence in parents, siblings and friends; socio-economic level of the family)

2. Alcohol:
2.1. Lifetime alcohol use
2.2. Lifetime heavy alcohol drinking
2.3. Current heavy alcohol drinking (past 30 days)
Primary outcome measures will be adjusted for recorded confounders (alcohol drinking in parents, siblings and friends; socio-economic level of the family)

3. Nutrition:
3.1. Food Frequency Questionnaire asks students to report the frequency of consumption of 12 items (in average weekly servings): vegetables; fruits; legumes (peas, beans, chick-peas); packaged snack foods; fried foods; potato chips; sparkling beverages; pies, ice-cream, and chocolate; fish; milk and yoghurt; cured or cooked meats and sausages (salami; ham); meat and cheese
3.2. Weekly prevalence of breakfast
Primary outcome measures will be adjusted for recorded confounders (socio-economic level of the family)

4. Physical activity:
4.1. Frequency of daily (hours per day) moderate (walking at least 30 minutes a day) or heavy (jogging; swimming; gym training) physical activity
4.2. Lifetime physical activity level practiced in a regular way

4.3. Current physical activity level practiced in a regular way (in last 30 days/in last 12 months)
Primary outcome measures will be adjusted for recorded confounders (physical activity levels in parents, siblings and friends; socio-economic level of the family).

Key secondary outcome(s))

1. Tobacco: Changes on attitudes and beliefs on tobacco smoking
1.1. Perceived health consequences of tobacco smoking (health risks for people who smoke one or more packets a day/smoke occasionally is negligible/high/low; selection of additives in cigarettes amongst a list of substances; nicotine is the carcinogen responsible of lung cancer [yes /no]; smoker becomes addicted to cigarettes if they smoke heavily for many years [yes/no])
1.2. Intent to use cigarettes in the near future
1.3. Beliefs about using if a friend offers a cigarette
1.4. Perceived social norm (In your opinion, how many adolescents tried to smoke, in percentage? how many adolescents smoke regularly, in percentage ? how many adults smoke, in percentage?)
1.5. Perceived social acceptability of smoking (If you uptake smoking in the next month, you will be more popular/more integrated with other boys and girls/you will feel more relaxed/informal and friendly/you will have more fun)
Secondary outcome measures will be adjusted for recorded confounders (smoking prevalence in parents, siblings and friends; socio-economic level of the family).

2. Alcohol: Changes on attitudes and beliefs on alcohol drinking
2.1. Perceived health consequences of alcohol drinking (health risks for people who drink alcohol 1 - 2 times per week/every day during meals/every day between meals is negligible/high/low; legal limit of alcohol assumption according to different types of drink; in half an hour the body discharges the quantity of alcohol of a beer can [yes/no]; men can tolerate alcohol in slightly higher doses than women [yes/no])
2.2. Intent to alcohol drinking or heavy alcohol drinking in the near future (next year).
2.3. Beliefs about alcohol drinking if some cool people invite you and your best friend to drink a spirit drink
2.4. Perceived social norm (In your opinion, how many adolescents drink alcohol between meals at least once/usually, in percentage? how many adolescents drink alcohol heavily at least once /usually, in percentage?)
2.5. Perceived social acceptability of smoking (If you drink alcohol in the next month, you will be more popular/more integrated with other boys and girls/ you will feel more relaxed/informal and friendly/you will have more fun)
Secondary outcome measures will be adjusted for recorded confounders (alcohol drinking in parents, siblings and friends; socio-economic level of the family).

3. Nutrition: Changes on attitudes and beliefs on nutrition -
3.1. Perceived health consequences of bad nutrition (health risks for people who have a bad nutrition is negligible/high/low; how many daily servings of fruit and vegetables are recommended by WHO?; which type of food is better to eat during the school break? (a light /heavy snack.)
3.2. Intent to increase consumption of fruits and vegetables/fish and legumes in the near future (next year).
3.3. Perceived social norm (In your opinion, how many adolescents eat recommended servings of fruits and vegetables, in percentage?)
Secondary outcome measures will be adjusted for recorded confounders (socio-economic level of the family).

4. Physical activity: Changes on attitudes and beliefs on physical activity
4.1. Perceived health consequences of alcohol drinking (health risks for people who dont practice any physical activity/use substances to improve their physical performance; creatinine consumption may cause weight increase/consumption of amino-acids may promote increase of muscle mass [yes/no]; recommended physical activity and dietary supplements for adolescents)
4.2. Intent to start or to go on practising a sport/to begin consumption of dietary supplements to improve ones physical performance in the near future (next year)
4.3. Beliefs about using drugs to improve your physical performance if your best friend offers you one.
4.4. Perceived social norm (In your opinion, how many adolescents practice physical activity regularly, in percentage?)
4.5. Perceived social acceptability of smoking (If you stop practicing any physical activity in the next month, you will increase your weight/you will be less tired/more irritable/you will not feel in a good form/you will worsen your physical appearance)
Secondary outcome measures will be adjusted for recorded confounders (physical activity levels in parents, siblings and friends; socio-economic level of the family).

Completion date
01/12/2012

Eligibility

Key inclusion criteria
1. Students aged 11 - 12 years, either sex, attending the 2nd class of the first-level secondary schools (FLS)
2. Students aged 13 - 14 years, either sex, attending the 1st class of second-level secondary schools (SLS)
3. Within 10 areas (Piacenza, Parma, Reggio-Emilia, Modena, Bologna, Imola, Ferrara, Ravenna, Cesena, Rimini; about 4.2 millions of inhabitants) of Emilia-Romagna region, Italy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 years

Upper age limit
14 years

Sex
All

Total final enrolment

5061

Key exclusion criteria
Students of participating schools with documented psychological or cognitive problems

Date of first enrolment
01/10/2010

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
Italy

Study participating centre
Public Health Unit
Bologna
Italy
40127

Sponsor information

Organisation
Emilia-Romagna Region (Italy)

ROR
https://ror.org/02edavb98

Funder(s)

Funder type
Government

Funder Name
Emilia-Romagna Region (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015		Yes	No
Results article	results	01/07/2019	15/04/2019	Yes	No