

A cluster randomised controlled trial for evaluating a comprehensive smoking prevention intervention in students aged 13 - 14 years old

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		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ER1

Study information

Scientific Title

A cluster randomised controlled trial for evaluating a comprehensive smoking prevention intervention for students aged 13 - 14 years old: a check of the School Smoke-free Policy and Peer Education program at school and attendance to the "Smoking Prevention Track" at the "Prevention Place" of the Italian League Against Cancer (LILT) in Reggio Emilia, Italy

Acronym

LILT-PrevPlace

Study objectives

To verify whether the comprehensive program carried out in the intervention schools could reduce the number of first class students that uptake smoking cigarettes during the following 2 years after the end of the comprehensive program, in comparison to the number of first class students starting smoking in 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 December 2010

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Smoking prevention

Interventions

Eighteen participating secondary schools located in the province of Reggio Emilia, Italy, have been paired according to the type of secondary school (technical school; high school) and the size of the school (number of students attending the first class in the 2008 - 2009 school-year).

In four pairs the pre-intervention survey has been conducted in the period December 2008 - January 2009. In the four schools of the experimental arm the intervention has been delivered during the period February - May 2009. The first follow-up survey both in experimental and control schools will be carried out in October - November 2009; the second follow-up survey in October - November 2010.

The other five pairs of schools will be carried out the pre-intervention survey in December 2009 - January 2010. The intervention will be delivered in the five school of the experimental arm in the period February - May 2010. The first and second follow-up surveys will be delivered in October - November 2010, and in October - November 2011, respectively.

Interventions:

The intervention in the experimental arm is characterised by:

1. Participation to the 4-hour "Smoking Prevention Track" (SPT), a workshop of 4 sessions at the LILT "Prevention Place" Center in Reggio Emilia, Italy
2. Participation to a School Smoking Prevention Program (check of the School Smoke-Free Policy and a Peer Education Program on smoking prevention)

1. "Smoking Prevention Track" (SPT) at the LILT "Prevention Place" Center:

The 4-hour SPT is characterised by four 40-minute sessions every first class of intervention schools has to attend during one morning. Every class is divided into two groups, and each group attends four different 40-minute sessions. The four sessions are led by LILT educators aged 25 - 35 years old:

1.1. Lab session: 10 minutes for explanation of physiology of the respiratory system; 20 minutes of laboratory trials for separating different smoking substances (tar, particulate matters, nicotine, carbon dioxide, nitrite oxides) using lab instruments. In the last 10 minutes a portable laser-operated aerosol analyzer with a sampling time of 2 minutes, is used in real time in order to measure Particulate Matters (PM2.5, PM10) when a cigarette is lit. Then a student expires on the analyzer, in order to show that the human respiratory system holds most part of PM2.5 during the breath.

1.2. Computer session: every student of a group at a personal computer fills in 3 - 5 score tests and calculate his/her overall score. At the end of every test, students can know his/her level according to his or her own final score. Tests are:

1.2.1. Self-evaluation test on physical and psychological wellness (all)

1.2.2. Self-evaluation test on stress levels (all)

1.2.3. Test on curiosity level about smoking (non-smokers)

1.2.4. The Fagerstrom Tolerance Questionnaire (smokers)

1.2.5. Self-evaluation test on motivation to quit (smokers)

1.2.6. Self-evaluation test on motivation to be a sustained non-smokers (former smokers)

1.3. Creative Writing session: the session begins with some readings about smoking. Then the session is divided into two parts:

1.3.1. "Smoking Signs": students divide a paper sheet into four parts in which they write four headings: smoking and emotions, thoughts, experiences, key-words. Every student fills in the four parts of the sheet using words and sentences, according to the headings.

1.3.2. "Personal Feeling of Smoking": students divide a paper sheet into three parts in which they write the following headings: feelings, beliefs, experiences. Every student fills in the three parts of the sheet using words and sentences, according to the headings.

1.4. Imagination session: after few minutes of relaxation and deep breathing in a room with

comfortable arm chairs, a novel is read aloud to the group. The novel describes the experience of smoking a cigarette during a Saturday night party in a disco-club. Students may identify themselves with the character. In the novel there are a lot of questions about the emotions that the character feels from smoking, and holding a cigarette.

2. Check of the School Smoke-Free Policy:

Compliance of the smoking ban and the presence of no-smoking signs in aisles, in teacher rooms, in toilets, and in other rooms of the schools, are checked and verified.

Peer Education Program on smoking prevention:

A group of self-selected peers of every experimental school (students attending the third class aged 15 - 16 years) are trained by LILT educators in a one-day session at the LILT "Prevention Place" Center and three 2-hour sessions at school. Trained peers organise a 2-hour meeting in every first class involved in the experimental arm. Peers may participate to the "Peer Award", a competition among schools of the experimental arm to select the best strategy and material created by peers themselves for presenting smoking issue in an innovative way to 13 - 14 year old students.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Lifetime cigarette use
2. Current cigarette use (past 30 days)
3. Frequent use of cigarettes (20 or more days of cigarette smoking in past 30 days)
4. Lifetime use of greater than or equal to 100 cigarettes

Primary outcome measures will be adjusted for recorded confounders (smoking prevalence in parents, siblings and friends; exposure to second-hand smoke at home and in cars; exposure to pro-tobacco and anti-tobacco advertisements; socio-economic level of the family).

Timepoints:

Before (first wave: December 2008 - January 2009; second wave: December 2009 - January 2010) and after the school intervention program:

First wave first follow up: October - November 2009; first wave second follow-up: October - November 2010

Second wave first follow up: October - November 2010; second wave second follow-up: October - November 2011

Secondary outcome measures

Changes on attitudes and beliefs on tobacco smoking and on tobacco industry conduct:

1. 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?)
2. Intent to use cigarettes in the near future (Do you think you will smoke a cigarette during the next year?)
3. Beliefs about using if a friend offers a cigarette (If one of your best friends offered you a cigarette, would you smoke it?)

4. Perceived social norm (In your opinion, how many adolescents smoke, in percentage?)
5. 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?)
6. 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?)

Secondary outcome measures will be adjusted for recorded confounders (smoking prevalence in parents, siblings and friends; exposure to second-hand smoke at home and in cars; exposure to pro-tobacco and anti-tobacco advertisements; socio-economic level of the family).

Timepoints:

Before (first wave: December 2008 - January 2009; second wave: December 2009 - January 2010) and after the school intervention program:

First wave first follow up: October - November 2009; first wave second follow-up: October - November 2010

Second wave first follow up: October - November 2010; second wave second follow-up: October - November 2011

Overall study start date

01/12/2008

Completion date

20/12/2011

Eligibility

Key inclusion criteria

Students aged 13 - 14 years old attending the first class of 16 - 18 secondary schools (for students aged 14 - 18 years old) in the province of Reggio Emilia (about 513,000 inhabitants), Italy.

Participant type(s)

Patient

Age group

Child

Lower age limit

13 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

3,000 - 3,500 students

Key exclusion criteria

Students attending the first class of participating schools with documented psychological or cognitive problems. Students have to fill in a detailed questionnaire on smoking before and after the intervention.

Date of first enrolment

01/12/2008

Date of final enrolment

20/12/2011

Locations**Countries of recruitment**

Italy

Study participating centre

"Luoghi di Prevenzione"

Reggio Emilia

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42100

Sponsor information**Organisation**

Italian League Against Cancer (LILT) (Italy)

Sponsor details

Provincial section of Reggio Emilia

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Sponsor type

Research organisation

Website

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ROR

<https://ror.org/02g2x7380>

Funder(s)

Funder type

Government

Funder Name

Ministry of Health (Italy) - Emilia-Romagna Region

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration