

# Acting by peer for tobacco prevention in young people

<b>Submission date</b> 20/10/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/12/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 16/04/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

In France, the issue of young people smoking remains a major challenge for public health, especially between the ages of 13 and 18, where the number of adolescents smoking goes from 5% at 13 years to around 38% at 18 years. There are a number of reasons why young people take up smoking. School failure, socio-economic and socio-cultural background all have a part to play in adolescents taking up smoking and maintaining the habit. Vocational students (students learning a trade rather than academic qualifications) are therefore at particularly high risk of using psychoactive substances (substances that effect the function of the brain), including tobacco. One of the most important factors is the environment, whether it be family, friends or peers. This peer influence can encourage or discourage smoking tobacco. Peer education, an approach whereby a person's peers are supported in encouraging others to adopt behaviours that are beneficial to health, therefore has the potential to change smoking behavior of adolescents. Indeed, it was demonstrated that the theory of planned behaviour (TPB) has been successful in promoting a number of health-benefiting behaviours. The main objective of this study is to measure the 24-month impact of a peer intervention (or programme) based on the theory of planned behavior on young people exposed to tobacco smoking.

### Who can participate?

Students attending vocational schools in France.

### What does the study involve?

During a period of three months, volunteer students develop a smoking prevention program with the help of practitioners. This program is then put to the test in their own schools. A total of 15 schools are involved. Seven of these are randomly allocated to the intervention group. The remainder are assigned to the control group. The participants are students in year 11 in all schools. The smoking prevention program is then run in those schools in the intervention group. The schools in the control group carry on as usual. All participating students attending a school in either group are asked to take part in the study for two years. They all complete an online questionnaire at the start of the study then at 3 months, 9 months and 15 months into the study. This questionnaire measures how much each student is smoking (tobacco or cannabis), drinking alcohol, tobacco addiction, and the students beliefs, norms and attitudes towards tobacco. Carbon monoxide levels are collected from each student at the end of the study.

What are the possible benefits and risks of participating?

The potential benefit for participants in this experiment is that they become less likely to take up smoking. No side effects are expected.

Where is the study run from?

Epidaure, Prevention Department of the Cancer Institute of Montpellier (France)

When is the study starting and how long is it expected to run for?

September 2013 to December 2016

Who is funding the study?

1. French National Cancer Institute,
2. Integrated Cancer Research Site, Montpellier (France)

Who is the main contact?

Professor Florence Cousson-Gélie

florence.cousson-gelie@univ-montp3.fr

## Contact information

**Type(s)**

Public

**Contact name**

Prof Florence Cousson-Gélie

**Contact details**

Epidaure, Prevention Department of the Cancer Institute of Montpellier

208, Rue des Apothicaires

Montpellier

France

34298

+33 (0)4 67 61 30 00

florence.cousson-gelie@univ-montp3.fr

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

2013-033

## Study information

**Scientific Title**

A randomized cluster controlled trial of P2P (Peer Two Peer) for evaluating a peer to peer and theory planned behavior-based program preventing tobacco smoking in vocational college

**Acronym**

P2P

**Study objectives**

The primary hypothesis is that the intervention will lead to a 10% decrease in the daily smoking prevalence between the intervention group and the control group after a 2-year follow-up.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

South-Mediterranean II ethics committee (Comité de Protection des Personnes (CPP) Sud Méditerranée I), 24/07/2013

**Study design**

Cluster randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

School

**Study type(s)**

Prevention

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Tobacco addiction

**Interventions**

This study compares an intervention group to a control group, randomised into clusters (professional schools and classes) and stratified in three departments of the Languedoc-Roussillon region (Hérault, Aude, Gard). It involves the development of a smoking prevention program made by peers, based on the theory of planned behaviour (TPB). Within interventional schools, the community program will be designed by stakeholders of the Student House (Maison des Lycéens) following a predefined framework. Every TPB dimension will be developed as actions for smokers (casual and / or dependent) or non-smokers. A "blank" action matrix will be initially proposed to students and will allow the distribution of the interventions suggested by the young people in corresponding boxes. The content will be tailored to each community-school needs. A technical committee will accompany the students teaching peers to help them

achieve their objectives. This committee aims to support creativity in each interventional Student House and bring supplementary elements if needed and according to their wishes. Six guidance sessions, each lasting a maximum of 1 hour, are proposed by the field committee to the Maison des Lycéens (MDL) intervention group peer educators.

The defined content for these sessions are as follows:

#### Session 1

1. Presentation of the teams, the aims and the protocol for the study
2. Constitution of the group of voluntary peer educators
3. If necessary, recommendations to enable young elected representatives of the MDL to recruit other peer educators amongst the non-elected college students (friends, leaders...)

#### Session 2, 3, 4

1. Gathering of the intervention propositions thought up by the youths of the MDL
2. Verification of the conformity between the interventions proposed by the youths and the Theory of Planned Behaviour (TPB)
3. Adding actions, if necessary, in order for the interventions to cover all the items of the TPB depending on the smoker status of the targeted peers (cf. table 1)
4. Propositions, if necessary, of "turnkey" examples of actions (cf. workshops 1 to 5)
5. Provisional budget estimate per action
6. Adjustment of the interventions/budget if necessary
7. Validation of the interventions

#### Session 5, 6

1. Provision of the necessary (material, financial) means
2. Contribution of knowledge and expertise in order to elaborate the tools if necessary
3. Support in the elaboration of the tools
4. Validation of the intervention tools

At the end of the school year, a day of meetings and exchanges between the college students of the MDLs, part of the intervention group, shall be organised. This day will take place at the Epidaure Centre and will gather youths from the MDLs, the local education authority, the Languedoc-Roussillon Regional Council and the ARS (Regional Health) representatives, as well as Public Health professionals (cf. team) and teams from the educational community.

The aims on this day for the youths of the MDL will be to:

1. Meet other young elected representatives of the MDL
2. Exchange on their own practical experiences
3. Learn about other proposed intervention tools
4. Present their own created intervention tools
5. Discuss with health, health education, nicotine related addiction specialists and health psychology professionals
6. Evaluate the knowledge and expertise acquired during the year
7. Programme the interventions for the following year

The actions proposed by the peer educators, with the support of the field committee, will be carried out throughout the next two school years. The pace of the interventions will be tailored to meet the requirements of each college according to the needs and modes of organisation. The length of each action will be adapted to the time realities of each school and will last between 45 minutes and 1.5 hours.

**Intervention Type**

Behavioural

**Primary outcome measure**

Prevalence of daily smoking at 24 months defined by a daily tobacco use of at least 1 cigarette validated by CO levels in exhaled air.

**Secondary outcome measures**

1. Using habits (tobacco, alcohol, cannabis),
2. Tobacco consumption modification characteristics (decrease, quitting)
3. Tobacco addiction and CAST score
4. Elements of TPB: behavioural norms, normative beliefs, control beliefs, attitudes, subjective norms, and perceived control
5. Environmental quality of high schools toward tobacco

Measured at baseline, then 3,9 and 15 months after baseline.

**Overall study start date**

01/09/2013

**Completion date**

31/12/2016

**Eligibility****Key inclusion criteria**

1. Students attending vocational schools aged 15-21
2. Girls and boys

**Participant type(s)**

Healthy volunteer

**Age group**

Mixed

**Sex**

Both

**Target number of participants**

15 clusters (college) with 200 students in each cluster

**Key exclusion criteria**

1. Participants who refuse give informed consent
2. Young people who cannot speak French

**Date of first enrolment**

01/12/2013

**Date of final enrolment**

30/06/2015

# Locations

## Countries of recruitment

France

## Study participating centre

**Epidaure, Prevention Department of the Cancer Institute of Montpellier**

208, Rue des Apothicaires

Montpellier

France

34298

# Sponsor information

## Organisation

French National Cancer Institute (Institut National du Cancer)

## Sponsor details

52 Avenue Morizet

Boulogne-Billancourt

France

92513

## Sponsor type

Government

## Organisation

Integrated Cancer Research Site (SIRIC)

## Sponsor details

ICM

208, Rue des Apothicaires

Montpellier

France

34298

## Sponsor type

Research organisation

## Organisation

French National Cancer Institute

## Sponsor details

### Sponsor type

Not defined

### Website

<http://en.e-cancer.fr/>

### ROR

<https://ror.org/03m8vkq32>

## Funder(s)

### Funder type

Government

### Funder Name

Institut National Du Cancer

### Alternative Name(s)

The French National Cancer Institute, INCa

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Research institutes and centers

### Location

France

### Funder Name

Integrated Cancer Research Site, Montpellier

## Results and Publications

### Publication and dissemination plan

We plan to publish the first results in 2016.

Some results were presented during congress :

1. Lareyre O., Stoeber-Delbarre A., Margueritte M., Cousson-Gelie F. (2014). One Year effects of P2P, a TPB-based program against tobacco for the students and by the students. EUSPR 5th Annual Conference and Members' Meeting, Palma Majorca, 16-18 October.

2. Cousson-Gelie F., Lareyre O., Margueritte M., Stoebner-Delbarre A. (2014). One year effects of P2P, a TPB-based program against tobacco realised by the students. Colloque Recherche interventionnelle contre le cancer : réunir chercheurs, décideurs et acteurs de terrain, Paris, 17 et 18 November.

### **Intention to publish date**

01/07/2016

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not expected to be made available

### **Study outputs**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Protocol article</a>	protocol	13/04/2018		Yes	No