

# Rationale, design and conduct of a school-based anti-smoking intervention: the “PEPITES” cluster randomized trial

<b>Submission date</b> 24/04/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 15/05/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/09/2019	<b>Condition category</b> Other	<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 smoking initiation rates amongst 11 to 16 year olds are worryingly high. Several studies show that early initiation is a strong predictor of tobacco addiction. Decreasing the age at which tobacco use starts represents a key challenge for reducing tobacco usage. It is also suggested that prevention actions need to be repeated regularly. The aim of this study is to assess the effectiveness of educational workshops covering the 4 years of secondary school both in reducing the tobacco initiation rate and the regular smoking rate of secondary school pupils.

### Who can participate?

Pupils in year 1 (grade 6) at participating secondary schools

### What does the study involve?

The six participating schools are randomly allocated to three groups of two each: one control group, who receive no educational workshops, and two different intervention groups with 2 workshops per year during 4 years. In one of the two intervention groups the two last workshops are dedicated to measuring the loss of taste due to tobacco smoking. The educational sessions are adapted to the age of the pupils, and tested and conducted by prevention professionals from the JDB Foundation. They are carried out during school time and last 45 minutes. In chronological order they cover the following themes: reasons for starting smoking, awareness of the risks taken, explanation of the marketing strategies of the tobacco industry, the mechanism of addiction and the effects on health. Smoking rates are measured by pupil questionnaire at the beginning of each year (October 2014, October 2015, October 2016, October 2017) and at the end of year 2 (May 2016) and 4 (May 2018)

### What are the possible benefits and risks of participating?

The possible benefits are to reduce tobacco onset and regular use in young people and consequently to reduce tobacco addiction in adult and all the diseases related to such use. There is no risk concerning educational workshops.

Where is the study run from?

1. JDB Foundation Cancer Prevention (coordinating center)
2. Collège Jean Moulin
3. Collège Roland Garros
4. Collège Pierre Mendès France
5. Collège Le Village
6. Collège Gérard Philipe
7. Collège Charles Péguy

When is the study starting and how long is it expected to run for?  
September 2014 to July 2018

Who is funding the study?

1. French National Cancer League
2. The Essonne committee of the Cancer League
3. The Essonne department health authority

Who is the main contact?

Mrs Stéphanie Vieira  
stephanie.vieira@fondationJdb.org

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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### Type(s)

Public

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

Commission Nationale de l'Informatique et des Libertés number 15-269

## **Study information**

### **Scientific Title**

Rationale, design and conduct of a school-based anti-smoking intervention: the "PEPITES" cluster randomized trial

### **Acronym**

PEPITES: Programme Essonnien de Prévention et Intervention Tabac En milieu Scolaire

### **Study objectives**

In France smoking initiation rates amongst 11 to 16 year-olds are worryingly high. Several studies show that early initiation to psycho-active substances is a strong predictor of tobacco addiction. Decreasing the age at which tobacco use starts represents a key challenge for reducing tobacco usage. Furthermore it is suggested that, prevention actions need to be repeated regularly. Implementing an intervention trial using educational workshops based on the theory of planned behaviour (TPB) and covering the 4 years of secondary school could be effective.

The study also tests the hypothesis that concrete consciousness of the harm caused by tobacco use could increase children's awareness regarding the harmful effects of tobacco and consequently improve their motivation to not start smoking or to stop if they have started. A tool, the electrogustometer, makes it possible to measure the taste sensitivity of the tongue - sensitivity which reduces significantly for a smoker from the first cigarettes regularly smoked.

PEPITES is an interventional research study in primary prevention, using the cluster randomized trial design. This methodology will allow assessing the effectiveness of the interventions both in reducing the tobacco initiation rate and the regular smoking rate of secondary school pupils. The study will also evaluate the process of the implementation of the study (what works, for whom, for what and in what circumstances) and thus will help to the transferability of the intervention.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

This research protocol has been validated by the CCTIRS, 06/10/2015, n°15 213Bis, to obtain the mandatory CNIL (French data protection authority) authorization, 11/21/2016, 2009002 v 0, and by the Ethical Evaluation Committee of INSERM Institut National de la Santé et de la Recherche Médicale: Institutional Review Board 00003888, 11/04/2015, file N° 15-269

### **Study design**

Cluster randomised 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 the contact details to request a patient information sheet

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

Tobacco use prevention

**Interventions**

The 6 schools were randomly allocated to 3 groups of 2 clusters each: 1 control group and 2 different intervention groups with 2 workshops per year during 4 years. In each school, all pupils in year 1 with a signed parental authorization (745 pupils covering 33 classes) have been included in the trial.

1. One group of 2 secondary schools with 2 educational workshops per school year; that is 8 interventions per secondary school over the 4 years
2. One group of 2 secondary schools with 2 educational workshops per school year; that is 8 interventions per secondary school over the 4 years, with one of the workshops dedicated to measure taste with the electrogustometer during the 3rd and 4th years
3. One control group of 2 secondary schools with no educational workshop

The educational sessions are adapted to the age of the pupils, and tested and conducted by prevention professionals from the JDB Foundation. They are carried out during school time and last 45 minutes. In chronological order they cover the following themes: reasons for starting smoking, awareness of the risks taken, explanation of the marketing strategies of the tobacco industry, the mechanism of addiction and the effects on health.

**Intervention Type**

Behavioural

**Primary outcome measure**

1. The prevalence of pupils having experimented (at least once) tobacco smoking at the end of year 2 and year 4 as compared to beginning of year 1 (comparison of the 2 intervention groups together versus the control group)
2. The prevalence of regular (at least weekly) cigarette smokers at the end of year 4 (comparisons of the 3 groups 2 by 2)

Outcomes collected by pupil questionnaire at the beginning of each year (October 2014, October 2015, October 2016, October 2017) and at the end of year 2 (May 2016) and 4 (May 2018)

## **Secondary outcome measures**

1. Experimentation with hookah, cannabis, electronic cigarettes
2. Perception of norms, attitudes and future intentions of the participants with regard to smoking
3. The various determinants which may have a role in starting smoking or becoming a regular smoker (gender, siblings, sporting activity, home area (ZUS), smokers in the entourage (parents, friends)

Outcomes collected by pupil questionnaire at the beginning of each year (October 2014, October 2015, October 2016, October 2017) and at the end of year 2 (May 2016) and 4 (May 2018)

The detailed evaluation of the process aims to study the context of the implementation of PEPITES in the school environment by identifying the external factors which might have an impact on the implementation (levers and obstacles) and on its effectiveness (such as: how well the rule forbidding smoking in the school is applied, other tobacco sessions carried out in the control schools, national campaigns, etc). The aim of this evaluation is to be able, if the results are positive, to transfer these interventions to other secondary schools. If the results are inconclusive, such an analysis might help to explain the reasons.

## **Overall study start date**

01/09/2014

## **Completion date**

01/07/2018

# **Eligibility**

## **Key inclusion criteria**

In each secondary school, all pupils in year 1 (grade 6) at the time of the survey, with a signed parental authorization form, have been included in the PEPITES trial  
Written parental authorization was requested for the whole duration of the trial after sending a letter which outlined the principal objectives of the trial and the intervention undertaken. The pupils could also refuse to participate even if the parents had given their authorization

## **Participant type(s)**

Mixed

## **Age group**

Child

## **Sex**

Both

## **Target number of participants**

750 pupils in 6 secondary schools of Essonne department

## **Key exclusion criteria**

All pupils (grade 6) either without parental authorization form or refusing to participate

## **Date of first enrolment**

15/09/2014

**Date of final enrolment**

15/12/2014

## **Locations**

**Countries of recruitment**

France

**Study participating centre**

**Collège Jean Moulin**

France

91290

**Study participating centre**

**Collège Roland Garros**

France

91180

**Study participating centre**

**Collège Pierre Mendès France**

France

91460

**Study participating centre**

**Collège Le Village**

France

91000

**Study participating centre**

**Collège Gérard Philipe**

France

91300

**Study participating centre**

**Collège Charles Péguy**

France

91120

**Study participating centre**  
**JDB Foundation Cancer Prevention (Coordinating center)**  
2-4 rue du Mont Louvet  
Fontenay-Lès-Briis  
France  
91640

## **Sponsor information**

**Organisation**  
JDB Foundation Cancer Prevention

**Sponsor details**  
2-4 rue du Mont Louvet  
Fontenay-Lès-Briis  
France  
91640

**Sponsor type**  
Charity

**Website**  
<http://fondationjdb.org>

**Organisation**  
University Paris-Saclay

**Sponsor details**  
Orsay Cedex  
Orsay  
France  
91405

**Sponsor type**  
University/education

## **Funder(s)**

**Funder type**  
Government

**Funder Name**

French National Cancer League (France)

**Funder Name**

The Essonne committee of the Cancer League

**Funder Name**

The Essonne department health authority

## Results and Publications

**Publication and dissemination plan**

The study protocol including statistical analysis plan, the informed consent form and the questionnaires will be available in French immediately following protocol publication to anyone who wishes to access the documents. The trialists intend to publish the study protocol in May 2018 in BMC Public Health Journal. They will publish the description of the population included in 2014 (N=744) in the trial (characteristics, tobacco habits, variables linked to tobacco use) in a French peer reviewed journal in 2018. The comparison of the 2 groups “intervention” versus the control group after 2 years of follow-up in 2019 in an international high-impact peer reviewed journal and, finally, the 3 groups comparison after 4 years in an international high-impact peer reviewed journal in 2020.

**Intention to publish date**

01/07/2020

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

The datasets generated during and/or analysed during the current study are/will be available upon request from Mrs Stéphanie Vieira (stephanie.vieira@fondationjdb.org). Written parental authorization was requested for the whole duration of the trial after sending a letter which outlined the principal objectives of the trial and the intervention undertaken. The pupils could also refuse to participate even if the parents had given their authorization. The self-assessment questionnaire contains a code which allows the answers from the same pupil to be followed from year to year. This numbered code was randomly generated and assigned to each pupil in the trial. The code is recorded in a list with the pupils' names which is held by the headmaster of the school in his role as a reliable third party (CNIL legislation). The data collected by the JDB Foundation are totally anonymous. The participants (or their parents) can only ask for being withdrawn from the data file via the director of the secondary school who is the only person having the list with the names and the corresponding number of anonymity. Anonymous data files could be provided to recognized scientist who provides a methodologically sound and validated proposal only after last publication (2020) and during 36 months\*. Such a request has to be addressed to the director of the JDB Foundation.

\*According to the CNIL (French data protection authority), data on computer support will be kept until the end of the study.



## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	31/07/2018	10/09/2019	Yes	No