

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

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Registration date 15/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/09/2019	Condition category 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

Mr Fabrice Cheruel

Contact details

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

Type(s)

Public

Contact name

Mrs Stéphanie Vieira

Contact details

2-4 rue du Mont Louvet
Fontenay-Lès-Briis
France
91640
+33 (0)1 60 80 64 65
stephanie.vieira@fondationJdb.org

Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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)

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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

Organisation

University Paris-Saclay

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**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?
Protocol article	protocol	31/07/2018	10/09/2019	Yes	No