

Four Year Results of a School-Based Anti-Smoking Intervention : The “PEPITES” Cluster Randomized Trial.

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Abstract

Background

PEPITES is an interventional research study, using a cluster-randomized design to assess the effectiveness of interventions both in reducing the tobacco initiation rate and the regular smoking rate of secondary school pupils.

Methods

The regional National Education authority designated 6 state secondary schools for the PEPITES trial. The 6 schools were randomly allocated to 2 groups: 1 control group (2 clusters), 1 intervention group (4 clusters) with 2 workshops per year during a 4 year period. The interventions targeted the variables of the Theory of Planned Behaviors and the reinforcement of psycho-social competencies. The 2 principal outcomes for the PEPITES trial were: the prevalence of pupils having experimented tobacco smoking at the end of years 2, 3 and 4, and the prevalence of regular cigarette smokers at the end of years 2, 3 and 4. The process was also evaluated. To compare the evolution of smoking experimentation over time in the two randomization groups, generalized linear mixed models with logit link function were used, considering the school and student as random effects.

Results

Globally, over time and regardless of the method of experimentation, the increase in the rate of pupils experimenting is slower in the intervention group than in the control group. The difference between the two groups during this period becomes significant ($p=0.03$) at the end of 9th grade. Concerning confirmed smokers, we note a slower but not significant increase in the percentage of cigarette smokers in the intervention group. For those who are smoking every day, no increase was noted in the intervention group, whereas a 2.8% increase was noted in the control group at the end of 9th grade.

Conclusions

The implementation of effective tobacco prevention actions in schools is important, as part of a programmed pathway from nursery school right through to high school. The implementation of the addictions plan for 2018-2020 should contribute to this policy but should rely on programs which have already proven to be effective in the medium and long term like this study.

Trial Registration

ISRCTN85812512. Retrospectively registered 15 May 2018.

Background

In France, the Escapad study [1] shows that between 2014 and 2017, for 17 year old teenagers, all the tobacco indicators were slowly decreasing: smoking initiation rates from 68.5% to 59%, as well as smoking from 44% to 34%. However this consumption is still higher than the European mean; out of 35 European countries, on the scale of decrease France is ranked 11th [2]. In this context, the French Social Affairs Ministry launched a national policy “the cancer plan 2014-2019” to try to reduce the number of people smoking daily to below 20% by 2024 [3]. The means to achieve this reduction focus in particular on actions directed at younger people in order to prevent *chronic non-communicable diseases related to smoking*.

In several systematic reviews of school-based smoking prevention, only 6-8 randomized trials have shown evidence of long term effectiveness [4 -5]. Furthermore the results depend on the type of interventions: only the trials combining social competences and resistance to social influences showed a statistically significant effect in preventing the onset of smoking at one year and longer follow-up (around 12% reduction). Significant effects were not detected in programs involving information only, social influences only or multi-modal interventions. In France, in 2013, no validated action had been shown to be effective in pushing back the age at which tobacco is first consumed and in reducing tobacco addiction among young people [6]. A report from a “group of experts” from INSERM [7] made propositions to promote tobacco prevention research in young people; it particularly suggested developing the psycho-social competencies in the various programs and promoting interventions which are evidence based. Since 2014, taking into account the recommendations of the INSERM report, various actions have been undertaken in France. They generally include the development of psycho-social competences; they rely on interventions throughout the entire school year with various annual sessions incorporated into the school program. Moreover, several studies having showed that early initiation to psycho-active substances (tobacco, cannabis, alcohol) is a strong predictor of tobacco addiction [8], and leads to stronger addiction and lower ability to stop smoking [9], various recent transfer studies have been dedicated to young people from 10 to 15 years old in France [10] (unplugged [11] , assist [12], good behavior game [13]). However in its 2017 report [14] the ‘Observatoire Européen des drogues et toxicomanie’ (OEDT) points to the absence of specifically marked interventions in the French school programs.

In 2018, an evaluation of the approach to prevention program was initiated by the “commission interministérielle de prévention des conduites addictives” (CIPCA); five programs have already been evaluated, 2 showed, in particular, significant decreases in tobacco onset and use [15].

In 2014, considering the above points, the “PEPITES” intervention trial (**P**rogram in **E**ssonne for the **P**revention of the **I**nitiation to **T**obacco through **E**ducation in the **S**chool environment) on tobacco prevention covering the 4 years of secondary school (\pm 11-15 years old) was implemented in the Essonne department by the Judlin De Bouville (JDB) Foundation for Cancer Prevention. Within the scope of the proposed educational workshops based on the Theory of Planned Behaviors (TPB)[16] and using a cluster randomized trial [17], we test the hypothesis that this health education program might increase the motivation of young people to not start smoking or to stop consuming. The present paper describes the

results of such a trial performed in 6 secondary schools in the Essonne department comparing an intervention and a control group followed during 4 years.

Methods

A detailed protocol has been published [18], and we present here the principal elements of the protocol.

1. Aims and study design

PEPITES is an interventional research study in primary prevention, using a cluster randomized trial design to assess the effectiveness of the interventions both in reducing the tobacco initiation rate and the further regular smoking rate of secondary school pupils. We also evaluated the process of the implementation of the study to help to ensure the transferability of the intervention [19-20].

2. Population selection and randomization

The Essonne National education authority designated 6 mixed-sex state secondary schools (from 6th grade to 9th grade) to participate in the PEPITES trial. In the original protocol [18], the 6 schools were randomly allocated to 3 groups of 2 clusters each:

- one group (I¹) with 2 educational workshops per school year over the 4 years of the secondary school duration,
- one group (I²) with 2 educational workshops per school year over the 4 years, but with one of the workshops dedicated to measuring taste loss linked to tobacco use during the 3rd and 4th years,
- one control group (C) of 2 secondary schools with no intervention planned.

Unfortunately the schools of the I² group had more than 40% of drop-out after 3 years of follow-up and we decided to join the I¹ and I² groups together for the analysis so as not to decrease too much the impact of the study.

Written parental authorization was requested for the whole duration of the trial.

At the start of the study in September 2014, 743 pupils were included in the trial, i.e. 94% of pupils in year 1 (grade 6) over the 6 schools.

3. Proposed educational interventions

The proposed interventions target one of the variables of the TPB and the reinforcement of psycho-social competencies. The educational sessions were adapted to the age of the pupils, tested and conducted by prevention professionals from the JDB Foundation. 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.

4. Outcome measures

4.1. Evaluation of the results

The two principal outcomes for the PEPITES trial are:

- the prevalence of pupils having experimented (at least once) tobacco smoking at the end of years 2, 3 and 4 as compared to the beginning of year 1,
- the prevalence of regular (at least weekly) cigarette smokers at the end of years 2, 3 and 4.

The secondary outcomes include: experimentation with hookah, cannabis and electronic cigarettes, perception of norms, attitudes and future intentions of the participants with regard to smoking. The various determinants which may have a role in starting smoking or becoming a regular smoker : gender, siblings, sporting activity, home area in a Deprived Urban Zone (DUZ), smokers in the entourage (parents, friends)... were also studied and reported.

Outcomes prevalence measures were only based on pupils' declarations.

4.2. Evaluation of the process

The detailed evaluation of the process aims to identify the external factors which might have an impact on the implementation (levers and obstacles) and on its effectiveness. 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 reason why.

5. Statistical power of the study

At the beginning of the study, the number of pupils that could be included in the trial was around 750 split into 3 groups of the same size. We calculated the rate of reduction of increase in the 2 principal outcomes we could detect, with a global risk α of 5%, a risk β of 20% and an intra-cluster correlation coefficient at base line of 0.020 (one-sided test).

1. Comparing Control (C) versus Interventions (I^1+I^2) on the reduction in increase of "*tobacco use initiation*" and considering that the intervention group (I^1+I^2) included ± 500 pupils and the control group (C) ± 250 ($N1/N2 = 1/2$), a significant reduction $\geq 5.5\%$ could be detected.
2. For the "regular smokers" criterion, a significant reduction $\geq 6.5\%$ at the end of year 4 could be detected.

Taking into account in the analysis the factors linked to these 2 outcomes and using appropriate multiple regression analysis and multi-level modeling should allow for an increase in the statistical power of the study.

6. The organization of the trial

After randomization, a steering committee was set up to identify all the necessary steps to ensure the successful implementation of PEPITES. In each secondary school, a key contact person was nominated so as to ensure coordination with the JDB Foundation team. This contact person was responsible for overseeing the overall organization of the interventions in the schools.

7. Data collection

The procedures and tools for data collection were created by the JDB Foundation team associated with a lecturer of the Paris-Sud XI University and were tested before the implementation of the trial. Regarding the process, qualitative methods (semi-directive interviews and completion of a log-book notifying absences, refusals, computers problem as well as comments relating to the data collection) were put in place. Regarding the pupils, the answers to the questions were collected by computerized and anonymous self-assessment questionnaires in classroom. The pupils were clearly informed that neither the teachers, nor their parents, nor anybody else could match their name to their answer. Pupils were also informed that they had the right to refuse to take part. The questionnaires cover the various determinants which may play a role in starting smoking and in becoming a regular smoker - the pupils' behavior with regard to tobacco use, that is: experimenter, regular or occasional smoker, ex-smoker, non-smoker.

8. Statistical analysis

Statistical analysis was performed using Stata software (version 13; StataCorp, College Station, Texas, USA). All tests were two-sided, with a Type I error set at 0.05. Categorical parameters were expressed as the number of subjects and associated percentages, and continuous data as mean \pm standard deviation or as median [inter-quartile range], according to statistical distribution. The baseline characteristics (beginning of 6th grade) of the 743 students included in the study were compared according to whether or not the students were lost to follow-up at the end of the study (end of 9th grade). Categorical variables were compared using the chi-squared test or Fisher's exact test, and quantitative data using the Student's t test or Mann-Whitney test, as appropriate. The Gaussian distribution was studied by the Shapiro-Wilk test and homoscedasticity by the Fisher-Snedecor test. The baseline characteristics of the students were also compared according to the randomization group (control vs. intervention) by the same statistical tests. In order to evaluate whether the evolution of smoking experimentation over time was different according to the two randomization groups, generalized linear mixed models with logit link function were used, considering the school and student as random effects. The dependent variable of the different models was binary (experimenter of: tobacco yes/no, cigarette yes/no, hookah yes/no, etc.) and the independent variables were the randomization group, the time (6th, 7th, 8th, beginning and end of 9th grades) and their interaction. Multi-variable analyses were implemented, considering the covariates according to epidemiological relevance (sex, DUZ, smoker at home, etc.). The evolution of smoking experimentation over time in each group (control vs. intervention) was also analyzed, with only time as an independent variable. As discussed by Feise in 2002 [21], the adjustment of Type I error was not proposed systematically but according to clinical and not only statistical considerations. Moreover, the factors associated with smoking were studied year by year, by generalized linear mixed models with:

experimenter yes/no as a dependent variable, the criterion studied (sex, country of birth, DUZ, etc.) as an independent variable, and the school as a random effect. Finally, sensitivity analyses were performed according to the same statistical analysis plan in order to evaluate the impact of missing data on the results: (i) on the sub-sample of students not lost to follow up, and (ii) on the sub-sample of students who participated in the five assessments.

Results

1. Description of the initial study population

We detail the principal characteristics of this population which was studied in a published article [22]. In September 2014, the start of the study in the 33 classes of 6th graders in the 6 chosen secondary schools, 790 pupils were contacted and 743 (94%) of them were included in the study. Reasons for non-participation (n=47) were: parental refusal (26 cases), pupil refusal (11 cases) and the absence of the pupil the day that the 1st questionnaire was distributed (10 cases).

Comparison between the 2 groups (Control (**C**) versus Intervention (**I**)) concerning the general characteristics of the 6th graders only showed (Table 1), among the variables being studied, two significant differences - pupils from the control group more often live in a DUZ and have more non-sporting extracurricular activities (cultural or other) than those in the intervention group.

More than a third of pupils have either their father or mother who are smokers and more than 30% of them are in contact with tobacco at home, of which 12% every day. Pupils in group **I** are a little more exposed to tobacco smokers at home than those in group **C** (40.1% vs. 32.8%, $p=0.057$).

The 6th graders who declared that they had already experimented with tobacco were 10.5% in group **C** and 11.9% in group **I** ($p=0.58$). We noted 45 experimenters of the hookah, of which 37 boys and 8 girls and 61 experimenters of cigarettes, of which 23 girls and 38 boys, with no difference between control and intervention groups. 2.4% of cases declared that they were smokers (0.7% every day and 1.7% occasional), with no difference between groups **I** and **C**.

2. Process evaluation

2.1. Carrying out the planned workshops

This study was made possible by private financing for the most part, which allowed us to propose 'turnkey' interventions which were free of charge to the schools.

In order to implement a randomized tobacco prevention trial in the school environment, it was necessary, first of all, to convince the academic management of the National Education ministry of the interest of such a methodology (randomization in 2 groups: intervention and control) leading to an « evidence based » evaluation and possible transferability to other schools. The partnership with Paris-Saclay university strengthened the quality of this study.

In order to address the disappointment of the randomized 'control' schools and to reinforce the importance of their passive participation in the study, the JDB Foundation had to offer, the first year, a pedagogic program dealing with physical activity whilst not interfering a priori with the study's objective.

Identifying a contact person for each school (often the school nurse as we are dealing with health issues) greatly helped us conduct the PEPITES study, despite frequent professional transfers (annual turn-over within the teaching staff in the 6 schools over the four year period). Additionally, within the scope of the Education Committee for Health and Citizenship (ECHC) lead by the headmaster and the school nurse, a significant amount of time was dedicated to tobacco prevention debates, which clearly made it easier to carry out the PEPITES study in the schools.

The interventions took place during normal school hours; this « intrusion » might have been viewed by the teachers as extra work and especially as a loss of time with regard to completing the curriculum for the year. In order to get the highest possible rate of participation, it was necessary to spend 16 extra 'catch-up' hours, on top of the 354 planned intervention hours over the 4 year period, to collect the data from pupils who were absent from the planned sessions. At the same time the teaching staff also had to organize activities for the 47 pupils who were not included at the start of the study.

In addition to the involvement of the teaching staff, it was also necessary to get the parents and pupils involved throughout the duration of the study. In order for nearly 100% of parents and pupils to agree to participate, they must clearly understand the objective of the study. Pupils must be reassured that their answers will not be shared with either their teachers or their parents, by clearly explaining the system of anonymous answers; this point was especially important as the questions concerned activities that, in principle, were banned.

The pupils liked the fact that we used digital tablets for the answers to the questionnaires and this was a fun and very useful tool for collecting personal data with a low risk of copying. This method was made possible thanks to the Essonne department council providing the tablets for all Essonne schools.

Planning of actions in advance allowed us to establish good relationships with the school staff and this was essential for the JDB Foundation team throughout the study. These relations were maintained through regular contact and annual meetings covering how the study was progressing. In this way we were able to follow the progress of programmed activities despite a wide variety of unforeseen problems (reserved rooms not available, pupils absent, teachers not informed, last minute timetable changes, unstable IT network, national strikes, terrorist attacks...). The individual needs and environment of each school were taken into account as far as possible: on the one hand a certain flexibility regarding logistical organization and planning of educational sessions, and on the other continued support throughout the PEPITES study between the schools and the project leader.

In total, this strict monitoring meant that, of the 8 interventions planned over the 4 years, 70% of pupils took part in 7 or 8 planned workshops, 13% in 5 or 6 and 17% only in half or less. However, regarding data collection, we were unable to prevent a drop-out rate of 33 % by the end of 9th grade.

2.2. Drop-outs

Table 2 shows the split of drop-outs over time in each of the 2 groups.

Pupil movements over time in each school cannot be controlled and the number of drop-outs is high (33 %) and aleatory variations over time in the 2 groups. Overall the drop-outs are significantly more often boys, living more often in a DUZ, and in a single parent home. They have also more often experienced a traumatic event (divorce, death, illness). Additionally and significantly they like school a lot less, have more contact with tobacco at home and have more friends who experiment with various products; finally, they have a more positive opinion regarding tobacco. Also they experiment significantly more with cigarettes and/or the hookah.

In order to evaluate the impact of the missing data on the overall results, sensitivity analyses were performed, on the one hand on pupils who had not dropped out at the end of 9th grade (n=497), and on the other on pupils who had participated in the 5 evaluations (n=470). The results described later on are similar whichever sample is chosen.

3. Factors influencing experimentation and tobacco smoking

We note that: being a boy, living in a DUZ, not liking school and feeling insecure there, having experienced a traumatic event, not living with your two parents, living with smokers, having daily contact with tobacco smoke, having friends who smoke and having a positive opinion of tobacco – all these factors increase the risk of experimenting with tobacco smoking, either cigarette, cigar, or hookah...

Nevertheless, over time we note a reduction in the gap between girls and boys from the 8th grade onward. Equally living with a single parent becomes less important with time. We observe that the feeling of insecurity at school and the fact of not liking school vary from one year to the next. The other factors remain more constant.

With regard to confirmed smokers, the low number of smokers does not allow us to analyze all these factors. Significant factors are mainly masculine sex, perceived insecurity at school, daily contact with tobacco smoke, and having a positive opinion of tobacco. These factors vary over time as those linked to experimentation.

4. Comparison of the principal outcomes over time in the 2 groups I/C

Overall, with time, and regardless of which type of experimentation, we note in each of the two groups a significant increase in the number of experimenters of tobacco from the start of grade 6 and right up to the end of grade 9: from 10.5 to 44.4% for the control group and from 11.9 to 34.3% for the intervention group. The progression in the number of experimenters is slower in the intervention group compared with the control group. The difference between the two groups during this period becomes significant ($p=0.03$) only at the end of 9th grade (Figure 1). The adjustment for risk factors linked to tobacco experimentation does not change the results (Table 3).

We also analyzed the number of experimenters over time according to the number of educational sessions attended (< 6 versus \geq 6) by pupils of the intervention group who were not experimenters at the start of the 6th grade (Figure 2). The effect of the number of sessions is not significant, perhaps due to a weak statistical power, but there is however a tendency in favor of pupils who attended 80% of the sessions.

Concerning the different types of experimentation with tobacco (Table 3) (cigarette, hookah, cannabis, taken on its own or not), the tendency is the same but only significant at the end of grade 9 when taken with cannabis (14.8% of experimenters in the control group, compared to 8.4% in the Intervention group ($p=0.03$)). For those who are « poly-experimenters » (experimenters of at least two products) , we observe at the end of 9th grade rates of 22.2% in the control group and of 15.8% in the intervention group ($p=0.08$).

5. Cigarette smokers (Table 4)

Overall the low number of smokers lessens the statistical power of the analysis, and only the cigarette smokers could be analyzed properly.

As with tobacco experimentation, the number of cigarette smokers increases significantly between the start and the end of the study, in both the Control group (from 2.2% to 6.2%) and in the Intervention group (from 2.5% to 3.9%). Concerning daily smokers, their number rises in the **C** group (0.9% to 3.7%) but remains stable in the **I** group (0.6%).

Discussion

Despite the reduction of statistical power due to drop-outs, this first randomized tobacco prevention study carried out in the school environment shows that educational workshops for pupils (11-15 years old) over a 4 year period and with two annual sessions can significantly reduce the increase in the number of experimenters by around 10 % and possibly of cigarette smokers by 2 to 3% at the end of 9th grade. We have seen that the drop-outs have all the characteristics of being at risk regarding smoking. As a result the difference between the 2 compared groups could have been decreased: fewer tobacco users to influence in stopping in the intervention group and more non-experimenters and non-smokers in the control group.

Various reviews in international journals (including 6 Cochrane reviews) have been carried out to identify the key data with respect to most effective ways to reduce tobacco addiction and in particular randomized studies (RCT's) using 'school-based » programs [23-24-25]. Few studies have analyzed the long term impact (>2 years) of school-based prevention programs. In 2008 S.E.Wiehe et al [4] selected 8 out of 177 randomized studies with long term follow-up (6th to 12th grade) with smoking prevalence as an outcome. Only one study showed decreased smoking prevalence in the intervention group. In 2012 R. Thomas [5] reports that in 49 studies that were reviewed the pooled analysis at one year follow-up or less showed no overall effect of intervention versus control. Only the combined social competence and

social influences curricula (6 RCT's) showed a statistically significant effect in preventing the onset of smoking at one year and longer follow-up.

In France no randomized study including this population of pupils (11-15 years old) and monitored over a 4 year period has been published as at today's date. Currently two transferability studies are in progress, covering this same population and following on from randomized studies carried out in Europe. The study '*Unplugged*' which has been validated at European level [23] was carried out in the Loiret department and was evaluated in 2016 [15]. The study is aimed at 11 to 14 year old pupils and consists of 12 one hour sessions carried out by specifically trained teachers. The program is based on the development of psycho-social competences, the correcting of normative beliefs and knowledge improvement. Initial results after 8 months show an increase in tobacco experimentation of 16.5% in the control group and only 8.5% in the intervention group. In comparison, the increase from 6th grade to 7th grade in our PEPITES study is 10.8% in the control group versus 6.8% in the intervention group. For confirmed smokers we observe in *Unplugged* a consumption of 3.7% still stable 8 months after, versus an increase of 4 to 9.8% for the control group. For PEPITES we observe a rate for smokers of 2.2% in 6th grade and of 2.4% in 7th grade and in the control group these rates are from 2.2% to 2.8%. These short term results are relatively consistent with each other despite the fact that initial consumption rates in the Loiret department are higher than in Essonne.

The Assist study transferred from the UK cluster randomized trial experience [24] consisted of training influential students to act as peer supporters outside the class room to encourage their peers not to smoke; primary outcome is a reduction in smoking; the population was the 12-13 year old school children followed during 2 years. Such a program is presently applied since 2016 in 19 "secondary schools". No results have been published yet.

Is it possible to predict that this reduction in experimentation might lead to a reduction in the number of smokers later in life?

Various authors have identified a dozen strategies concerning teenagers which are considered to be 'validated or promising' in reducing the number of smokers in the long term [25]. Consequently, actions based on developing the psycho-social competences of children are universally approved, as are those delivering school-based interventions including multiple sessions over the whole curriculum and beginning early as part of a wider tobacco control strategy. Our trial was based on these two types of strategy and has been increasingly effective over time which leads us to hope that the results will be long-lasting. In order to demonstrate this we would have had to continue our follow-up in high school, but at the present time and in the context of the French system this would be extremely difficult to do.

Transferability

We have compared our results with data from cohort studies of the general population in France. When considering tobacco behavior in 2014, the included PEPITES population was representative of the school children in 1st year of secondary school in France with in PEPITES **11.4%** [CI95%*: 9.5 - 13.5%] versus **10%**

in France of tobacco initiation and **2.4%** [*1.3-3.5%] in PEPITES versus **2%** of regular smokers in France. The split between the different types of experimentation (alone or with other types of tobacco experimentation) are comparable to the French data in the HBSC 2014 study [2], that is:

- hookah: **6.2%** in PEPITES [* 4.3-7.7%] versus **5.5%** in HBSC;
- cannabis: **0.7%** in PEPITES [* 0.1-1.3%] versus **1.5%** in HBSC;
- e-cigarette: **8.3%** in PEPITES [* 6-10%] versus **9.8%** in HBSC.

In 2018, our population is 15 years old, its tobacco experimentation rate is **37.6%** [* 33.6-41.6%], (44.4% [*36.4-51.6%] in the control group and 34.3% [*32.5-36.1%] in the intervention group) as compared to **37.4%** in France (26). Tobacco consumption is **6.2%** [*2.5-9.9%] in the control group and **3.9%** [*1.9-5.9 %] in the intervention group, in France this rate is **13.6%** [27]. Daily smoking rates remain low: **3.7%** [*1.7-6.7 %] and **0.6%** [*0.08-1.4 %] for PEPITES as compared to **6.5%** in France.

In our study the rate of tobacco experimentation is very close to the rate in France as a whole, but tobacco consumption is now lower in Essonne, even in the control group despite the initiation rate being identical indicating a quicker decrease in young tobacco smokers in this area.

Conclusion

The vulnerability of teenagers to drugs (alcohol, tobacco, cannabis) is well established [28] and justifies early prevention actions being taken. The implementation of effective prevention actions is necessary in the school environment, supported by specific interventions from nursery school right through to high school [29], but also in the immediate entourage (parents and educators). A lack of prevention actions constitutes a serious failure. The implementation of the new addictions plan 2018-2020 should support this policy but it must be based on programs which have proven their effectiveness over the mid to long term. This strategy having showed its efficacy within a randomized trial can therefore be suggested for implementation more extensively in secondary schools wanting to lead anti-tobacco actions with their pupils. The deliberately detailed analysis of the process shows the different obstacles and levers when carrying out such interventions in the school environment and it allows us to make some recommendations regarding the transfer of the results in other situations.

Implementing health actions in schools relies on certain key principles [19], which are:

- Clarity of information for all management actors, health professionals, teachers, pupils, parents,
- Understanding and acceptance of the strategy by all parties,
- Limiting to the strict minimum the work demanded of the school staff,
- A planned and reactive organization and regular contact with a dedicated project coordinator identified for the duration of the project.

Abbreviations

CCTIRS Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé

CIPCA Comité Interministérielle de Prévention des Conduites Addictives

CNIL Commission Nationale de l'Informatique et des libertés

DSDEN Direction des Services Départementaux de l'Education Nationale

ESCAPAD Enquête sur la Santé et les Consommations lors de l'Appel de Préparation A la Défense

HBSC Health Behavior in School-Aged Children

INSERM Institut National de la Santé et de la Recherche Médicale

JDB Judlin De Bouville

PEPITES Program in Essonne for the Prevention of the Initiation to Tobacco through Education in the school Environment

TPB Theory of Planned Behaviors

ZUS Zone Urbaine Sensible / **DUZ** – Deprived Urban Zone

Declarations

Ethics approval and consent to participate

This research protocol has been validated by the Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé (n°15 213Bis) previously to obtain the mandatory Commission Nationale de l'Informatique et des Libertés authorization (2009002 v 0) and by the Ethical Evaluation Committee of Institut National de la Santé et de la Recherche Médicale (INSERM): Institutional Review Board 00003888 (file N° 15-269). 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 methods. The pupils could also refuse to participate even if the parents had given their authorization.

Availability of data and materials

The data sets used and/or analyzed during the present study will be available from the corresponding author on reasonable request. Inform Consent forms and questionnaires are available in French.

Competing interest

SV, CL, FC, BP and HSG declare that they have no conflicts of interest.

Funding

The intervention approach has been developed by the sponsor JDB Foundation in Essonne thanks to the financial support of the French National Cancer League, the Essonne committee of the Cancer League and the Essonne department health authority.

The sponsor is in charge of study design, organization, management, data collection, analysis, interpreting, reporting and the decision to submit the report for publication, including ultimate authority over any of these activities.

Funders decide to give financial support following scientific expertise.

A steering committee composed of JDB foundation research workers and 2 referents from each high school included in the trial is in charge of regularly overseeing the good evolution of the trial and solving the problems if any.

Authors contributions

- S.V is the coordinator of the study
- S.V and F.C participated in the preparation, testing and carrying out of evaluations, running of educational workshops, data-management.
- C.L and B.P are the persons responsible for PEPITES data input (methodology, statistical analysis)
- F.C is the scientific referent for tobacco addiction and EGM,
- H.S.G is the scientific referent for the trial methodology and analysis.

S.V, F.C, H.SG participated in the protocol building and in its submission for funding; they read and approved the final protocol and agree to publish it.

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Author's Information

This study PEPITES adheres to CONSORT guidelines.

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Tables

Table 1: Baseline characteristics of the two groups (control and intervention)

	Total (n=743)	Control (n=229)	Intervention (n=514)	p
Gender (%Female)	371 (49.9)	110 (48.0)	261 (50.8)	0.49
Median age (years)	11.50 ± 0.45	11.52 ± 0.44	11.48 ± 0.45	0.30
Live in urban sensible zone	160 (21.5)	61 (26.6)	99 (19.3)	0.024
Single parent family	207 (27.9)	60 (26.2)	147 (28.6)	0.50
Practice a sport activity in a club	527 (70.9)	166 (72.5)	361 (70.2)	0.53
Other activity (out of school)	253 (34.1)	95 (41.5)	158 (30.7)	0.004
Want to go to school to learn	522 (70.3)	151 (65.9)	371 (72.2)	0.086
Don't like school very much	289 (38.9)	90 (39.3)	199 (38.7)	0.88
Tobacco smoker(s) at home	281 (37.8)	75 (32.8)	206 (40.1)	0.057
Cigarette smoking friend(s)	103 (13.9)	29 (12.7)	74 (14.4)	0.53
Tobacco experimenter	85 (11.4)	24 (10.5)	61 (11.9)	0.58
Cigarette experimenter	61 (8.2)	15 (6.6)	46 (8.9)	0.27
Hookah experimenter	45 (6.1)	14 (6.1)	31 (6.0)	0.97
Tobacco smoker	18 (2.4)	5 (2.2)	13 (2.5)	0.78

Data is presented as number of pupils (associated percentage) or as mean ± standard deviation.

Table 2: Drop-outs over time by group

	Number of pupils lost to follow-up...	After the 1 st assessment (beginning of 6 th grade)	After the 2 nd assessment (beginning of 7 th grade)	After the 3 rd assessment (beginning of 8 th grade)	After the 4 th assessment (beginning of 9 th grade)
Control	67	18 (8%)	19 (9%)	21 (11%)	9 (5.4%)
Intervention	179	46 (9%)	32 (7%)	42 (10%)	59 (15.5%)

Table 3: Comparison control/intervention for tobacco experimentation

	Témoïn			Intervention				
	N	n (%)	p ¹	N	n (%)	p ²	p ³	p ⁴
Experimenter ^A								
Start 6 th grade	229	24 (10.5)		514	61 (11.9)			
Start 7 th grade	211	45 (21.3)	0.002	464	87 (18.7)	0.002	0.37	
Start 8 th grade	189	105 (24.5)	<0.001	429	105 (24.5)	<0.001	0.65	
Start 9 th grade	166	47 (24.9)	<0.001	381	114 (29.9)	<0.001	0.24	
End 9 th grade	162	56 (33.7)	<0.001	335	115 (34.3)	<0.001	0.13	0.030
		72 (44.4)						
Cigarette Experimenter ^B								
Start 6 th grade	229	15 (6.6)		514	46 (8.9)			
Start 7 th grade	211	25 (11.8)	0.057	464	70 (15.1)	0.003	0.86	
Start 8 th grade	189	33 (17.5)	0.001	429	77 (17.9)	<0.001	0.99	
Start 9 th grade	166	83 (21.8)	<0.001	381	83 (21.8)	<0.001	0.22	
End 9 th grade	162	40 (24.1)	<0.001	335	80 (23.9)	<0.001	0.13	0.17
		48 (29.6)						
Hookah Experimenter ^B								
Start 6 th grade	229	14 (6.1)		514	31 (6.0)			
Start 7 th grade	211	27 (12.8)	0.017	464	42 (9.1)	0.068	0.49	
Start 8 th grade	189	33 (17.5)	<0.001	429	57 (13.3)	<0.001	0.81	
Start 9 th grade	166	39 (23.5)	<0.001	381	76 (19.9)	<0.001	0.63	
End 9 th grade	162	56 (34.6)	<0.001	335	82 (24.5)	<0.001	0.34	0.19

	Témoïn			Intervention				
	N	n (%)	p ¹	N	n (%)	p ²	p ³	p ⁴
Cannabis Experimenter ^B	229	2 (0.9)		514	2 (0.4)			
Start 6 th grade	211	3 (1.4)	0.59	464	10 (2.2)	0.025	0.29	
Start 7 th grade	189	10 (5.3)	0.018	429	15 (3.5)	0.003	0.47	
Start 8 th grade	166	17 (10.2)	0.001	381	26 (6.8)	<0.001	0.59	
Start 9 th grade	162	24 (14.8)	<0.001	335	28 (8.4)	<0.001	0.76	0.029
End 9 th grade								
Poly-experimenter ^C	229	6 (2.6)		514	17 (3.3)			
Start 6 th grade	211	9 (4.3)	0.34	464	28 (6.0)	0.043	0.72	
Start 7 th grade	189	21 (11.1)	0.001	429	33 (7.7)	0.003	0.77	
Start 8 th grade	166	27 (16.3)	<0.001	381	48 (12.6)	<0.001	0.39	
Start 9 th grade	162	36 (22.2)	<0.001	335	53 (15.8)	<0.001	0.29	0.082
End 9 th grade								

p1 : analysis in sub-group (control group) in relation to initial time (start 6th) ; p2 : analysis in sub-group (intervention group) in relation to initial time (start 6th) ; p3 : interaction between time (in relation to the start 6th) and the group (intervention in relation to control), considering an adjustment for the sex, living in deprived urban zone, living with cigarette or hookah smokers, having friends who are cigarette smokers, having friends who are hookah smokers, feeling safe in the school, and liking school or not; p4 : comparison of the groups at the end of 9th.

A : one or several products ; B : more or less one other product ; C : experimenter of at least two products among cigarettes, hookah and cannabis.

Table 4: Comparison control/intervention for cigarette smokers

	Control			Intervention				
	N	n (%)	p ¹	N	n (%)	p ²	p ³	p ⁵
Cigarette smokers (currently)								
Start 6th grade	229	5 (2.2)		514	13 (2.5)			
Start 7th grade	211	6 (2.8)	0.56	464	11 (2.4)	0.80	0.88	
Start 8th grade	189	9 (4.8)	0.070	429	10 (2.3)	0.41	0.75	
Start 9th grade	166	9 (5.4)	0.026	381	11 (2.9)	0.18	0.51	
End 9 th	162	10 (6.2)	0.006	335	13 (3.9)	0.033	0.39	0.26
Daily cigarette smoker								
Start 6th grade	229	2 (0.9)		514	3 (0.6)			
Start 7th grade	211	2 (0.9)	0.70	464	3 (0.6)	0.84	0.98	
Start 8th grade	189	5 (2.6)	0.081	429	4 (0.9)	0.44	0.93	
Start 9th grade	166	4 (2.4)	0.11	381	4 (1.0)	0.37	0.76	
End 9 th	162	6 (3.7)	0.023	335	2 (0.6)	0.90	0.14	0.073

p^1 : analysis in sub-group (control group) in relation to initial time (start 6th) ; p^2 : analysis in sub-group (intervention group) in relation to initial time (start 6th) ; p^3 : interaction between time (in relation to the start 6th) and the group (intervention in relation to control), considering an adjustment for the sex, living in deprived urban zone, living with cigarette or hookah smokers, having friends who are cigarette smokers, having friends who are hookah smokers, feeling safe in the school, and liking school or not; p^4 : comparison of the groups at the end of 9th.

Figures

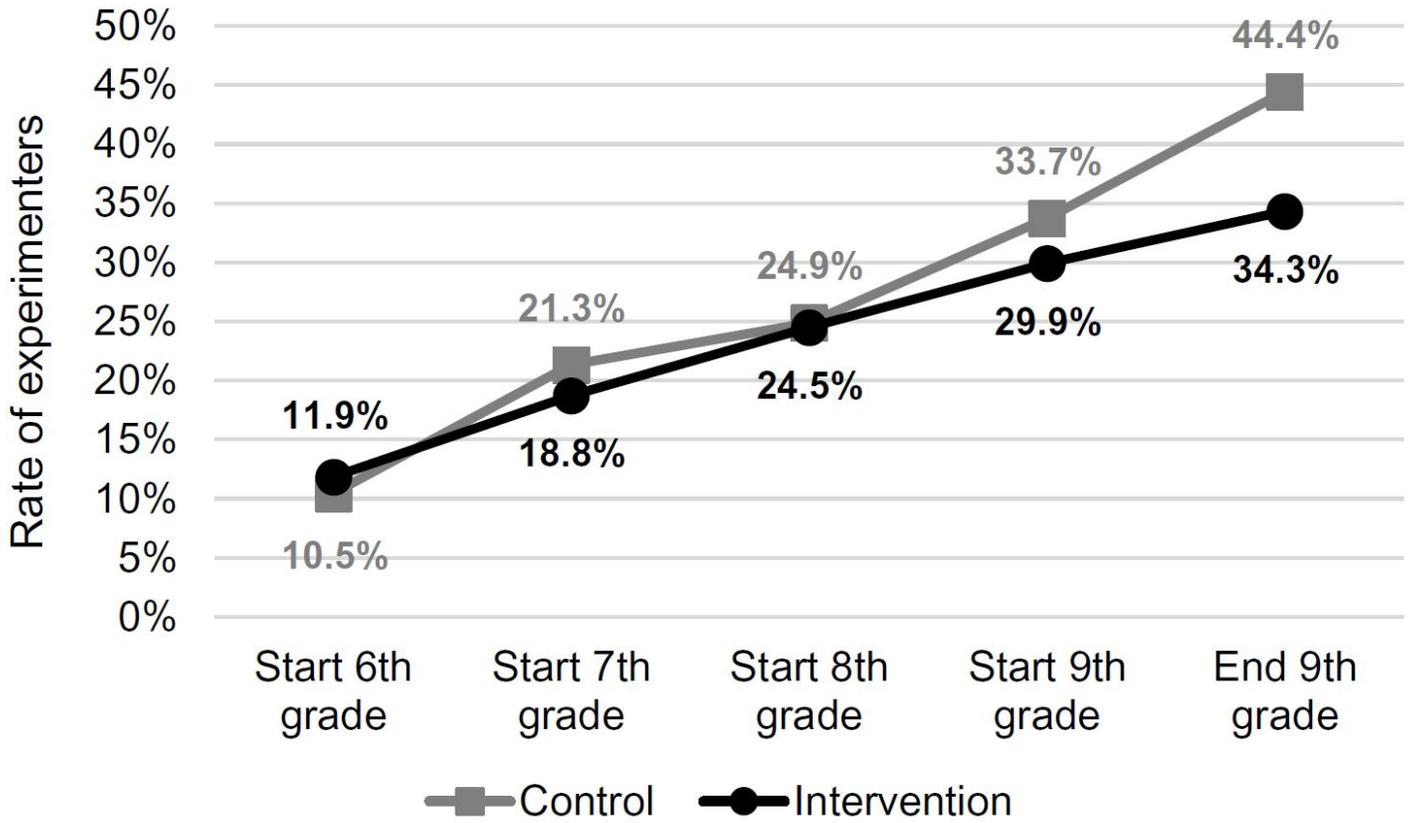


Figure 1

Tobacco experimentation according to school level in 2014-2018 (%).

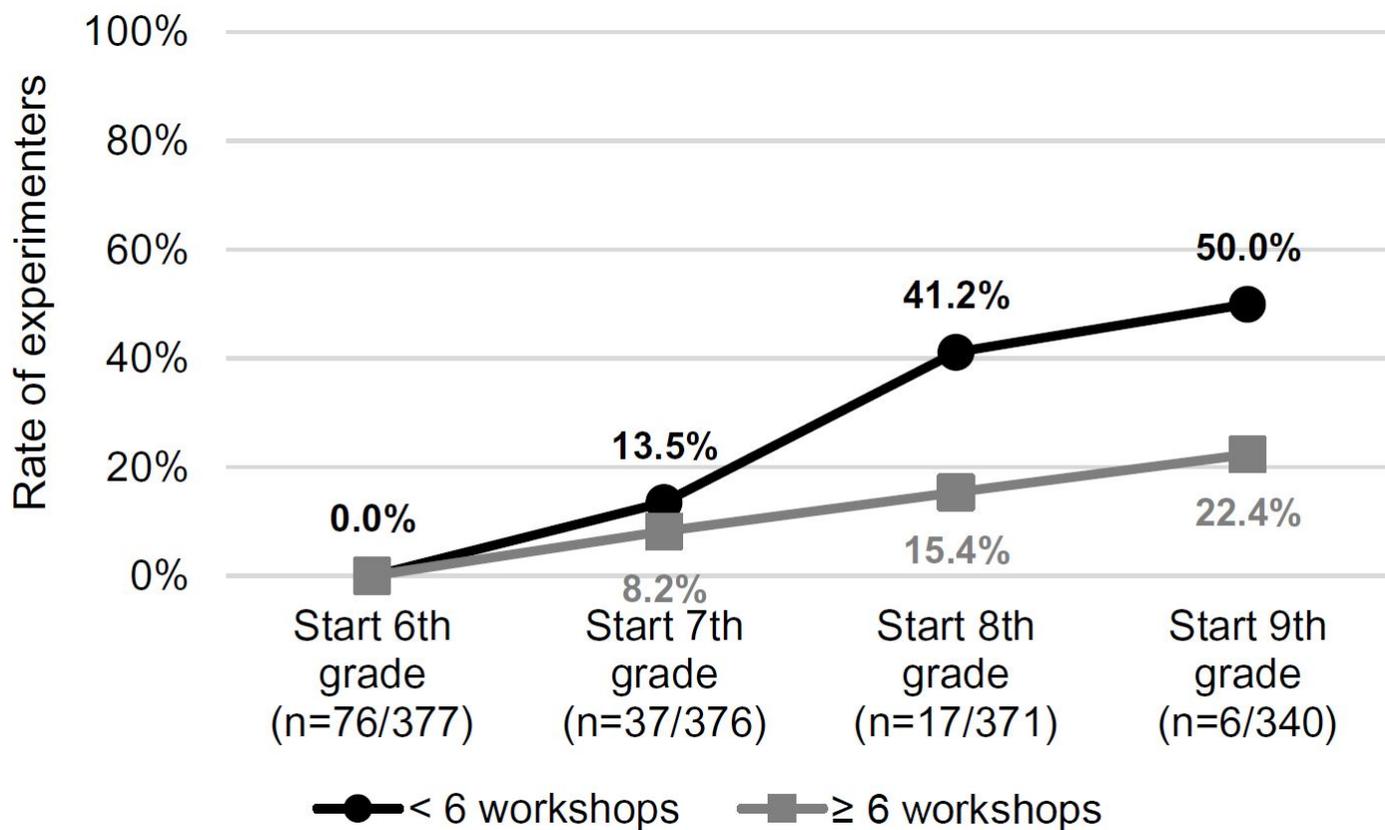


Figure 2

Tobacco experimentation by secondary school pupils according to participation in educational workshops between 2014 and 2018 (%) (n=X/Y), X refers to the group "<6 workshops" and Y refers to the group "≥ 6 workshops" At the start of 9th grade, the rate of experimenters is 50% in the "<6 workshops" group, there are 3/6 of them who are experimenters.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [CONSORT2010Checklist.pdf](#)