BMJ Open

Factors and motivations associated with use of e-cigarette among primary care patients in a prospective cohort study: *e*-TAC study protocol

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To cite: Kinouani S, Castéra P, Laporte C, *et al*. Factors and motivations associated with use of e-cigarette among primary care patients in a prospective cohort study: *e*-TAC study protocol. *BMJ Open* 2016;**6**: e011488. doi:10.1136/bmjopen-2016-011488

► Prepublication history and additional material is available. To view please visit the journal (http://dx.doi.org/10.1136/bmjopen-2016-011488).

Received 11 February 2016
Revised 27 April 2016
Accepted 3 May 2016

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ABSTRACT

Introduction: While the relationship between electronic cigarette use and smoking has often been studied, the association between electronic cigarette use and socioeconomic factors has received less attention. This is a study protocol aiming to describe the relationship between the consumption of psychoactive products (in particular: smoking) or some socioeconomic factors and the evolution of the use of electronic cigarette in primary healthcare over 1 year.

Methods and analysis: Electronic cigarette, Tobacco, Alcohol and Cannabis (*e*-TAC) is a prospective multisite cohort study, including 473 patients at baseline and carrying out in general practices in the Aquitaine area (France). The volunteer patients participated in the study regardless of their initial reason for consultation. They filled out a self-administered questionnaire at baseline and will also do so after 12 months by phone, email or letter. The study will focus on the factors that explain the experimentation with or the current use of the electronic cigarette, as well as factors associated with their evolutions over time using multivariate logistic regression modelling or Cox regression modelling.

Ethics and dissemination: This study received ethical approval from the University of Bordeaux Committee for the protection of persons. It was also approved by the National Commission for Data Processing and Freedoms. Findings will be submitted for publication in peer-reviewed journals and we will disseminate them by presentations at national or international conferences.

Trial registration number: RCB: 2015-A00778-41; Pre-results.

Strengths and limitations of this study

- To the best of our knowledge, it is the first cohort study about the electronic cigarette use carrying out in general practices in France.
- The trainees' involvement in the recruitment of patients will probably improve the feasibility of the study. Thanks to their involvement and enthusiasm, the study will not represent an excessive workload for their supervisors.
- The study will focus on socioeconomic factors that may determine the use of electronic cigarettes. It will describe their use based on smoking, as well as on the consumption of alcohol and cannabis. Where relevant, it will also examine this use in subgroups of the French population. These factors and subgroup analyses have received little attention until now.
- The selection bias will be reduced by the online questionnaire proposed at 12 months. Furthermore, to minimise loss to follow-up, three forms of communication will be used: letter, email and phone.
- Since this is a prospective study on a small sample, the sample size of 473 participants and a 1-year follow-up period were established for reasons of feasibility. Causal relations cannot be inferred.

INTRODUCTION

Electronic cigarettes (e-cigarettes) are battery-operated devices that provide an aerosol for inhalation that sometimes contains nicotine. Their use is increasing worldwide and mainly concerns smokers.[1–5] Although their long-term health effects are unknown, their use might be less harmful than smoking according to experimental studies, although this remains to be confirmed in clinical research studies.[6–8]

While the relationship between smoking and e-cigarette use has been studied several times, the relationship between e-cigarette use and socioeconomic factors such as education level or occupational category is less clear.[1 4 9–19]

The main reason reported for e-cigarette use is the desire to stop smoking.[9 11 14 16 18 20–24] However, other reasons are sometimes declared, particularly in young adults: the desire to use a product delivering nicotine but which is less harmful than smoking, curiosity,

the search for a new experience, the lower cost compared with smoking, the feeling of regulating one's use, etc.[11 23–28] To the best of our knowledge, no prospective studies specifically focusing on e-cigarette use among the elderly or people with chronic diseases have been published. There have been no studies on e-cigarette use among people using several products such as alcohol, tobacco and cannabis too.

The Health Barometer study is a repeated French cross-sectional survey carried out over the phone. Samples were taken among a random representative French population aged 15–75 years. According to this study, 26% of the French population had tried an e-cigarette and 6% were current users in 2014.[29] As in many other countries, e-cigarettes were mainly used by smokers and former smokers. According to these authors, the socioeconomic factors associated with the e-cigarette use among smokers in France were: income level, occupational status and socioprofessional category.[29]

The main objective of this study is to describe among experimenters of at least one substance (tobacco, alcohol, cannabis, or e-cigarette) the factors associated with the evolution of e-cigarette use over 12 months: factors associated with the transition from non-use to experimentation; factors associated with the transition from experimentation to current use; factors associated with cessation of use. The secondary objective is to describe the factors associated with experimentation and current use of e-cigarettes. The third objective is to describe the frequency of motivations reported for e-cigarette use and those associated with the most common motivations.

METHODS AND ANALYSIS

The Electronic cigarette, Tobacco, Alcohol and Cannabis (*e*-TAC) study is a multicentre, prospective, observational cohort study that has currently been underway for 1 year in Aquitaine, South-West France.

Recruitment

The recruitment is almost finished and took place from May until October 2015 in eight general practices. It was performed in two steps: first, recruitment of general practices; second, recruitment of eligible patients.

Recruitment of general practices

Each general practice trainee in Bordeaux University does an internship in three different general practitioner (GP) offices for at least 6 months. An email describing the *e*-TAC project was sent to all 430 trainees in their second or third year of specialisation in Bordeaux University at the beginning of March 2015. Trainees who intended to do their internship from May to October 2015 and were willing to help recruit patients during this period were invited to contact the first author (SK). Another author (BG) also talked to the trainees about the *e*-TAC project during general practice courses at the end of March 2015. The trainees' recruitment is explained in figure 1. Fifteen volunteer trainees contacted SK. She selected five of them as *e*-TAC research ambassadors on the basis of their motives and internship locations. The steering committee decided that the study should take place only in two locations per trainee so that they could continue to learn general practice without being overloaded by the requirements of the study. SK sent the study protocol by email to trainees, and then she met each of them in individual interviews. She explained to them the protocol and answered their requests during this meeting. SK also organised a meeting with the five trainees and taught them how to explain the study to the patients. She showed them the various documents for the patients and trained them to inform patients during a role play.

At the beginning of March 2015, SK sent an email to all GPs who usually were training supervisors in general practice in Aquitaine in order to explain the study to them. The email also informed them that some future trainees would be participating as research ambassadors. After the meetings between SK and the 5 selected trainees, she sent a new email to inform the 10 supervisors concerned that their future students were willing to participate. She proposed a phone conversation to talk about it and obtain their oral agreement. Two training supervisors of the same trainee refused to participate. In the end, four trainees and their eight training supervisors in general practice accepted to participate. Patient recruitment was conducted by these four research ambassadors and their eight supervisors. These eight private general practices are the investigation centres of the study.

Recruitment of patients

Eligible patients were then recruited. The target population was patients followed by GPs. The sample consisted of patients who met the following inclusion criteria: older than 18 years; agree to participate by signing and dating a consent form; must understand French; be able to fill in a questionnaire on paper; must attend a consultation in one of the eight investigation centres regardless of the reason for the consultation; must have completed the self-administered questionnaire for inclusion (totally or partly); must have smoked tobacco or drunk alcohol or used cannabis or used an e-cigarette at least once in their lifetime.

Patients under guardianship or trusteeship for property were excluded. Patients seen at home visits were excluded.

A large poster and flyers announced the study in the waiting rooms of the investigation centres. The questionnaires were available in the waiting rooms with detailed letters of information and consent forms. If they requested it, the patients received a full explanation of the study from the trainees. Each volunteer patient filled in a consent form and a questionnaire and then put them in two separate boxes in the waiting room.

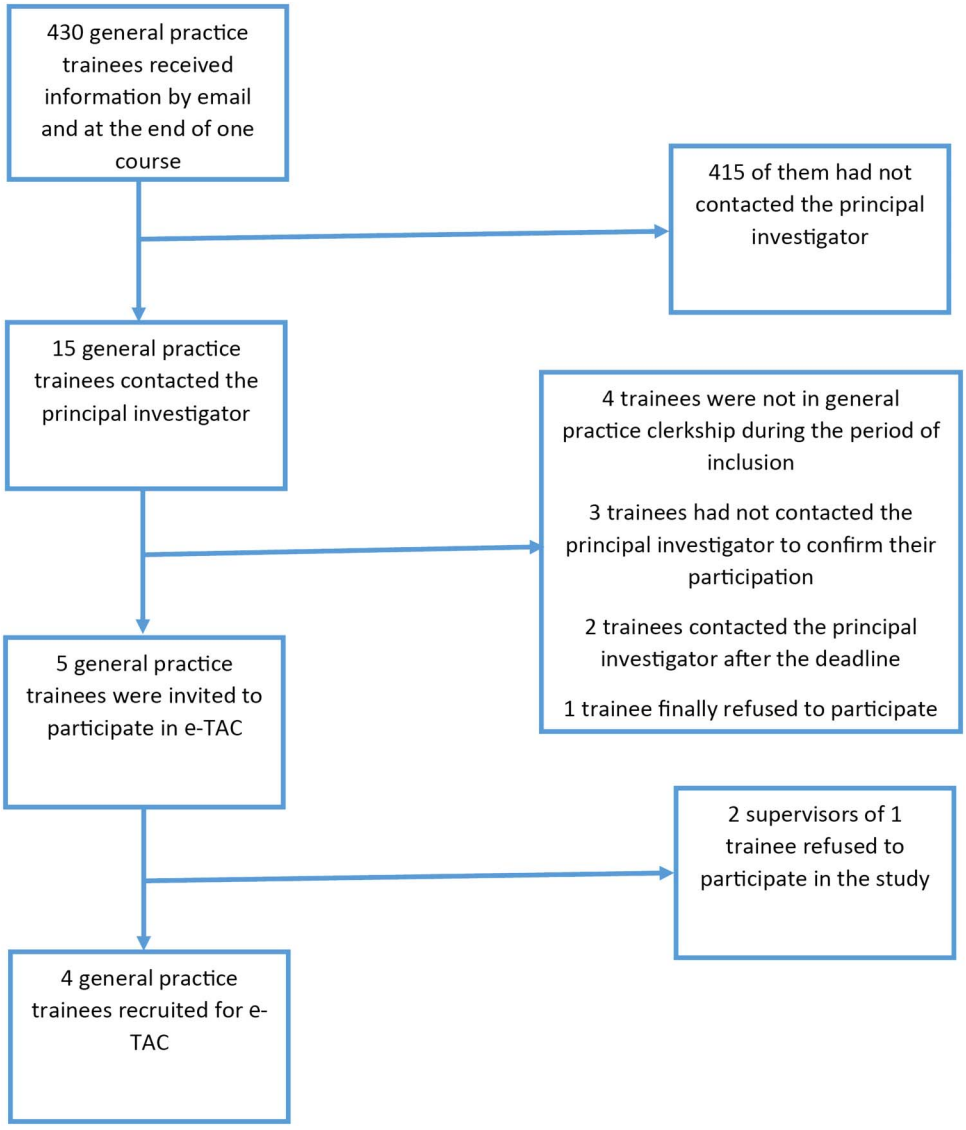

Figure 1 Flow chart of trainee recruitment in the *e*-TAC study (France).

Data collection

All data were collected on a declarative basis. Baseline data were collected from May to October 2015 using a self-administered paper questionnaire designed by SK, PC and BG. It was amended by a specialist in social communication who had validated it in a pilot study. The design and process for validating the baseline paper questionnaire is shown in an additional file (see online supplementary file S1). Before the start of the study, the first author sent an Excel file to the students and taught them how to transcribe data collected with the paper questionnaire. She also checked the quality of data collection and resolved the trainees' problems by conference call once a month during the study.

Follow-up data will be collected by the same trainees on average 12 months later, from May to October 2016. A link to an online questionnaire will be sent to all patients who agreed to give their emails for inclusion with MailChimp. This questionnaire will be created with LimeSurvey software. Reminders will be sent out once a week in the absence of answers. After four reminders or in the absence of an email address, the follow-up questionnaire will be sent by post with a postage-paid envelope. In the absence of any answer by email or by post, patients having given a phone number will be contacted by phone by trainees. They will be asked to say how they wish to receive the follow-up questionnaire and if they still wish to participate. If they no longer wish to participate, the reasons for non-participation will be requested. Trainees will call patients in blind without knowing their characteristics at baseline. Inclusion and follow-up are illustrated in figure 2.

Each patient received an identification number at baseline that was written on the questionnaire and the consent form. Once both forms were in the two separate boxes, the analysis of baseline data became anonymous.

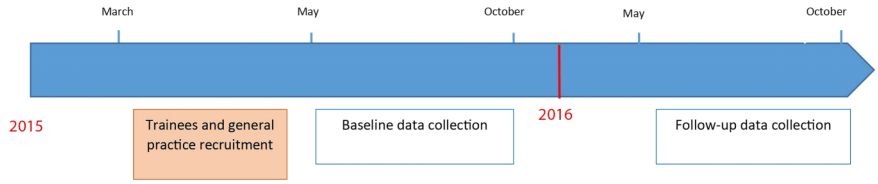

Figure 2 Data collection in the *e*-TAC study (France).

Outcomes and covariates

The main outcome is the evolution of e-cigarette use over 12 months. This evolution will be studied in three ways: transition from non-use to experimented use at 12 months; transition from experimented use to current use at 12 months; transition from current use to cessation at 12 months. Experimented use is defined as reporting use at least once in a lifetime. Current use is defined as reporting ongoing use at the time of the survey, either occasionally or regularly. Experimentation and current use will be explored through two binary variables.

Six exposure factors will be studied: (1) demographic factors at baseline such as age (continuous variable), living in rural or urban area and sex; (2) factors related to smoking, the use of alcohol or cannabis, collected at baseline and after 12 months (see online supplementary file S2). Nicotine dependence will be explored by the Cigarette Dependence Scale-5 (CDS-5) developed by Jean-François Etter. It was preferred to the Fagerström test for Nicotine Dependence owing to its better psychometric properties.[30–32] The first three questions of the Alcohol Use DIsorders Test (AUDIT) will be used to explore the problematic use of alcohol.[33 34] The problematic use of cannabis in the 12 months prior to the survey will be explored by five questions from the Cannabis Abuse Screening Test (CAST). This tool was developed in 2002 by the 'Observatoire Français des Drogues et des Toxicomanies', a national non-profit public interest group with a scientific mission. Its psychometric properties have mostly been studied among adolescents;[35–37] (3) socioeconomic factors at baseline (categorical variables): occupational status, education level, marital status, housing status and current opinion of one's own financial situation; (4) presence of chronic diseases at baseline and at 12 months: migraine, hypertension, diabetes, cardiovascular diseases, sleep disorders, asthma, other respiratory diseases, cancer; (5) motivations for taking part in the e-cigarette experiment, collected at baseline and at 12 months (multiple choice question) and (6) motivations for current e-cigarette use at baseline at 12 months (multiple choice question).

Statistical analysis

All estimates will be calculated on the total sample and in subgroups if relevant: young adults (18–30 years), premenopausal women (18–50 years old), the elderly (75 years and more), people with at least a chronic disease, people who use at least two of the following products: alcohol, tobacco, cannabis. Simple descriptive statistics will be used to describe each variable at baseline or 12 months: mean, SD, median for continuous variables; number and proportion for categorical or binary variables.

Three comparisons will be made to answer the main objective. The first will compare non-users who will have evolved into experimented users to non-users whose status is unchanged at 12 months. The second will compare experimented users at baseline who become current users in 12 months to experimented users whose status is unchanged. The third will compare current users at baseline who have stopped their use at 12 months to those whose status is unchanged.

Three other comparisons will be made to answer the second objective. These comparisons will be performed at baseline and then at 12 months. First, the experimenters of the e-cigarette will be compared with non-users. They will then be compared with current users. Third, non-users will be compared with current users. In the end, the prevalence of the various motivations for e-cigarette use will be estimated for experimentation and then for current use with their 95% CIs. The factors associated with the most common motivations for each use will be analysed.

Univariate and multivariate analyses will also be performed. The Student's t test or the non-parametric test will be used for univariate analysis of continuous variables. Univariate comparison of proportions will be performed using the χ^2 test. Fisher's exact test will be used when the theoretical count in cells is <5. Multivariate comparisons will be performed by modelling with Cox regression for the main objective and logistic regression with fixed effects for the second objective. Patients with missing data on their e-cigarette use at baseline will not be included in the models. Stratified analyses by age, sex or smoking status will also be carried out if relevant. Significance will be set to 0.05 and all tests will be two-tailed.

A strategy of missing data management is planned with multiple imputation. Sensitivity analyses will be performed to compare the results with complete data and those after multiple imputation.

Sample size calculation

Since several hypotheses are studied, it was difficult to calculate a minimum sample size. The relationship between smoking and e-cigarette will also be analysed. According to the literature, a difference of at least 7.8% could be expected in current e-cigarette use between current smokers and non-smokers.[29 38–40] A sample of at

least 280 participants would detect this difference with a power of 80% power and α=0.05.

The prevalence of experimentation of e-cigarette use in studies ranges from 2.7% to 50.6%.[15 41] The prevalence of use in the past 30 days ranges from 1.2% to 41%.[15 20] According to the Health Barometer study, the prevalence of experimentation and current use in 2014 was 26% and 6%, respectively.[29]

It was necessary to include at least 385 participants in the study to estimate the prevalence of different types of e-cigarette use with an accuracy of 5% and a confidence level of 95%. Finally, the aim was set for at least 385 participants at the end of follow-up. Assuming an attrition rate of 40% between the beginning and the end of the study, at least 539 patients needed to be included by the end of the recruitment stage. We managed to include 473 patients in October 2015.

Pilot study

A pilot study was conducted in April 2015 for 1 week in two general practices in Aquitaine that did not participate in the study. The two trainees in each pilot centre explained the project to patients and asked them to complete the questionnaire as if they were actually going to participate in the study. Questionnaires, consent forms and information letters were available in the waiting rooms. At the end of the consultation, the trainees asked the patients to fill in a new short questionnaire. It assessed the clearness, accuracy and shortness of the information letter and the first questionnaire with Likert scales ranging from strongly agree to strongly disagree. The final option allowed patients to make free comments. The patients agreed to participate in the study (19 participants for 24 proposed questionnaires). The main reason for exclusion was the absence of information about guardianship or trusteeship for property. Minor changes were made to the letters and questionnaire based on this pilot study.

DISSEMINATION

Each patient gave written consent before being included in the study.

The findings will be introduced in different national or international conferences. We intend to submit our findings in peer-reviewed journals.

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Acknowledgements The authors thank Aurélie Lazès-Charmetant, a specialist in social communication, for revising the questionnaire and Ray Cooke forcopyediting the manuscript. They thank the eight investigators: Dr Sandrine Allaire-Sauquet, Dr Victor Carre, Dr Daniel Falcinelli, Dr Farina, Dr Jean-Paul Gainard, Dr Philippe Jourde, Dr Georgine Labadie-Monnier and Dr François Petrègne. They thank their four research ambassadors and their colleagues who participated in the study: Alice Sane, Anne-Laure Cutuli, Marc Delbos, Nicolas Germemont, Charlotte Rychen and Benjamin Soen.

Contributors SK is the principal investigator who conceived the study. SK, PC and BG contributed to the study design. FP was one of the training supervisors who undertook patient recruitment. SK and CL wrote the manuscript. All the authors read and approved the final version.

Funding This study was funded by the College of Aquitaine general practitioners/teachers.

Disclaimer This sponsor had no influence on the study design, the collection, analysis or interpretation of data, on the writing of the manuscript or on the decision to submit it for a publication.

Competing interests None declared.

Ethics approval The study protocol was approved by the Local Committee for the Protection of Persons of Bordeaux University (approval number 2015-A00778-41). It was also approved by the National Commission for Data Processing and Freedoms (approval number 1838811).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Data will be available for all authors from the end of the cohort study by emailing the corresponding author.

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