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Evaluation of an intervention aimed at improving the support for smoking cessation of patients by general practitioners

Submission date
11/09/2024

Recruitment status
No longer recruiting

Registration date
25/11/2024

Overall study status
Completed

Last Edited
25/11/2024

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Each year, more than 75,000 deaths in France are attributable to smoking. Despite strong measures that have reduced smoking, the number of daily smokers has stagnated since 2019. Studies show that smokers accompanied by a health professional are at least 70% more likely to succeed in quitting smoking than those who try to quit smoking alone. However, the majority of smokers try to quit on their own, and health professionals underestimate the demand for support and its effectiveness. The objective of the study is to evaluate how well tools intended to support and encourage general practitioners in supporting smoking cessation work.

Who can participate?
General practitioners (GPs) from mainland France who do not work exclusively in a hospital, in a clinic and/or in a company.

What does the study involve?
GPs are recruited via an online panel and another contact file comprising around 37,000 GPs on the whole. GPs have to complete a recruitment questionnaire, at the end of which they are randomly allocated to one of two groups: (1) Control, receiving nothing, (2) Treatment, receiving a kit by post. The kit includes: 1/ an information sheet on carrying out a brief intervention in three stages: Screen, Advise and Refer; 2/ leaflets to be placed in the waiting room with a questionnaire to survey patients about their smoking, information on the benefits of cessation and the role of GPs in helping smoking cessation; 3/ a poster to attract patients' attention to the questionnaire. The use of the tools is planned over a period of 4 weeks, at the end of which a follow-up questionnaire is sent to GPs from both groups. GPs report the number of patients with whom they talked about smoking cessation, and if they proposed a support, during the last full working day. To evaluate the impact of the tools, the results in GPs who received these tools are compared to those of GPs who did not receive them.

What are the possible benefits and risks of participating?
Participants in the intervention group can continue to use the tools beyond the duration of the experiment. Participants in the control group can download the tools after answering the follow-

up questionnaire. Participants in both groups receive compensation of 30 euros if they respond to both questionnaires (recruitment and follow-up). No risk is identified.

Where is the study run from?
Santé publique France, the French national public health agency, manages the study. The experiment takes place in general medicine practices.

When is the study starting and how long is it expected to run for?
September 2022 to May 2024

Who is funding the study?
Santé publique France and the French national health insurance.

Who is the main contact?
Romain Guignard, romain.guignard@santepubliquefrance.fr

Contact information

Type(s)
Public, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness of the provision of tools for general practitioners to support smoking cessation, compared to no intervention

Acronym
Tabac-Pro

Study objectives
1. The intervention increases the number of patients with whom the doctor talks about smoking cessation
2. The intervention increases the likelihood that they will offer support to patients (medication prescriptions, referral to another healthcare professional, or suggestion of a follow-up appointment)
3. The intervention increases the number of patients for whom they screen smoking status
4. The intervention increases the proportion of smokers for whom they assess the level of dependence
5. The intervention increases the proportion of smokers for whom they assess the motivation to quit
6. The intervention increases the proportion of smokers for whom they suggest reducing their consumption
7. The intervention increases the proportion of smokers for whom they recall the benefits of quitting smoking

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/01/2024, Behavioural Insights Team’s internal ethics committee (58 Victoria Embankment, London, EC4Y 0DS, United Kingdom; +44 7306118521; bobby.stuijfzand@bi.team), ref: FR000088

Study design
Interventional two-arm simple-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Prevention of tobacco smoking

Interventions
General practitioners (GPs) have to complete an online recruitment questionnaire, at the end of which they are randomized to one of both groups by an integrated algorithm.

GPs in the intervention group receive a kit by post with:
- an information sheet on carrying out a brief intervention for smoking cessation in three stages: Screen, Advise and Refer.
- leaflets to be placed in the waiting room with a questionnaire to survey patients about their smoking, information on the benefits of cessation and the role of GPs in the management of cessation
- a poster to attract patients' attention to the questionnaire.

GPs in the control group receive no intervention (usual care).

The use of the tools is planned over a period of 4 weeks, at the end of which a follow-up questionnaire is sent to both groups.

Intervention Type
Behavioural

Primary outcome measure
Number of patients with whom a GP talked about smoking cessation during the last full working day, at 4 weeks, self-reported in a follow-up questionnaire.

Secondary outcome measures
Probability that a GP offers smoking cessation support during the last full working day, at 4 weeks, self-reported in a follow-up questionnaire.

Overall study start date
12/09/2022

Completion date
10/05/2024

Eligibility

Key inclusion criteria
1. Practice in mainland France
2. Not work exclusively in a hospital, in a clinic and/or in a company

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
1500

Total final enrolment
800

Key exclusion criteria
Work exclusively in a hospital, in a clinic and/or in a company

Date of first enrolment
15/01/2024

Date of final enrolment
08/03/2024

Locations

Countries of recruitment
France

Study participating centre
Santé Publique France
12, rue du Val d'Osne
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Sponsor information

Organisation
Santé Publique France

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Sponsor type
Government

Website
http://www.santepubliquefrance.fr/

ROR
https://ror.org/00dfw9p58

Funder(s)

Funder type
Government

Funder Name
Santé Publique France

Funder Name
Caisse nationale de l'Assurance Maladie

Alternative Name(s)
French National Health Insurance Fund, National Fund for Health Insurance, CNAM

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
France

Results and Publications

Publication and dissemination plan
Planned publication in an English-language peer-reviewed journal and in a French professional journal.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Romain Guignard (romain.guignard@santepubliquefrance.fr). Anonymized data can be shared with external teams after analysis of the project by Santé publique France and signing of a confidentiality commitment.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			20/09/2024	No	Yes