

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

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| <b>Submission date</b><br>11/09/2024   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                                  |
| <b>Registration date</b><br>25/11/2024 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>25/11/2024       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> 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](mailto:romain.guignard@santepubliquefrance.fr)

## Contact information

### Type(s)

Public, Principal Investigator

### Contact name

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Scientific

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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.stuijtzand@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

Saint-Maurice

France

94415

# Sponsor information

**Organisation**

Santé Publique France

**Sponsor details**

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dpps-raf@santepubliquefrance.fr

**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? |
|---|---------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> |         |              | 20/09/2024 | No             | Yes             |