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# Impact of a smartphone application on smoking cessation: a randomized controlled trial

**Submission date**
26/04/2018

**Recruitment status**
No longer recruiting

**Registration date**
17/05/2018

**Overall study status**
Completed

**Last Edited**
09/06/2025

**Condition category**
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
In Switzerland, lung cancer is the first cause of cancer death, and in women, lung cancer will soon surpass breast cancer as the first cause of cancer death. Thus, effective smoking cessation interventions are necessary, and these interventions need to be widely disseminated. Smartphone-based support can reach thousands of smokers and have a substantial public health impact, in particular in the majority of smokers who would otherwise try to quit by themselves, without help and with little chance of success. The Stop-tabac fully-automated application (app) for smartphones was launched in 2012 and is now mature and ready for a test of its efficacy. It was ranked among the best five smoking cessation apps worldwide in a recent academic review. The services available on this app include: immediate feedback during episodes of craving and tobacco withdrawal symptoms; an interactive “coach” that provides individually-tailored counseling messages based on responses to a questionnaire (personal profile); a discussion forum (“The Tribe”) where participants receive support from other users; fact sheets; a calculator of cigarettes not smoked, money saved, and years of life gained; and a module on nicotine replacement therapy that includes personalized feedback. The aims of this study are to assess whether this app is effective for smoking cessation, to measure the size of its effect, and to examine whether the outcome is influenced by the personal characteristics of the participants.

Who can participate?
Daily cigarette smokers aged over 18

What does the study involve?
Participants are randomly allocated to either use the Stop-tabac app for 6 months or to use a placebo (dummy) app. Participants are followed up after 1 week, 1 month and 6 months to ask whether they have stopped smoking.

What are the possible benefits and risks of participating?
Participants will not be paid. They will have a chance of accessing a comprehensive smoking cessation app for smartphones, and they will contribute to the science on this topic. There is no

risk associated with the behavioral program and the data collection procedure. There is a risk that data may be accessed by hackers. The researchers will make every effort to minimize this risk by using appropriate security measures.

Where is the study run from?
ISG - Faculty of Medicine - University of Geneva (Switzerland)

When is the study starting and how long is it expected to run for?
December 2016 to November 2020

Who is funding the study?
Swiss National Science Foundation

Who is the main contact?
Prof. Jean-François Etter

# Contact information

### Type(s)
Scientific

### Contact name
Prof Jean-François Etter

### ORCID ID
https://orcid.org/0000-0002-1426-3157

### Contact details
ISG-Campus Biotech
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# Additional identifiers

### Protocol serial number
SNF 320030_179369

# Study information

### Scientific Title
Impact of a smartphone application on smoking cessation: a randomized controlled trial

### Study objectives
An application for smartphone will help smokers stop smoking.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
Received confirmation that ethics committee approval is not needed 16/05/2018, Commission Cantonale d'Ethique de la Recherche (CCER) (Rue Adrien-Lachenal 8, 1207 Geneva, Switzerland; messaging@basec.swissethics.ch), ref: Req-2018-00356.

## Study design
Two-arm parallel-group individually randomized “placebo”-controlled trial

## Primary study design
Interventional

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Cigarette smoking

## Interventions
The trialists will randomly assign 5200 smokers to either using the Stop-tabac application for smartphones for 6 months or to use a placebo application. Stop-tabac is a fully-automated application (“app”) for smartphones that includes:
1. Immediate feedback during episodes of craving and tobacco withdrawal symptoms
2. An interactive “coach” that provides individually-tailored counseling messages based on responses to a questionnaire (personal profile). These automated messages are sent regularly during 6 months
3. A discussion forum (“The Tribe”) where participants receive support from other users
4. Fact sheets; a calculator of cigarettes not smoked, money saved, and years of life gained
5. A module on nicotine replacement therapy that includes personalized feedback
Follow-up after 1 week, 1 month and 6 months.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
-

## Primary outcome(s)
Self-reported smoking cessation at 6 months (no puff of tobacco in the past 4 weeks). All data will be self-reported via online questionnaires. Participants can use any device to answer (smartphone, tablet, laptop, desktop). There will be no biochemical validation of smoking status. Assessed 4 times: at baseline, and 1 week, 1 month and 6 months after the participant’s target smoking cessation date.

## Key secondary outcome(s))
1. Point prevalence of smoking abstinence at 6 months (no puff of tobacco in the previous 7 days)
2. Russell Standard (<5 cigarettes in the past 6 months plus no puff of tobacco in the past 7 days)
3. Abstinence of any tobacco and e-cigarette use at 6 months (no use in the previous 7 days)

4. Motivation to quit
5. Quit attempts (number and duration)
6. Confidence in ability to quit
7. Use of nicotine therapy
8. Use of e cigarettes and heated tobacco products

All data will be self-reported via online questionnaires. Participants can use any device to answer (smartphone, tablet, laptop, desktop). There will be no biochemical validation of smoking status. Assessed 4 times: at baseline, and 1 week, 1 month and 6 months after the participant's target smoking cessation date.

### Completion date
04/11/2020

## Eligibility

### Key inclusion criteria
1. Daily cigarette smoker
2. Has been a daily smoker for at least one year
3. >18 years old
4. Sets a target quit date within one month of enrollment and commits to quit on this date
5. Provides informed consent online
6. Commits to answer all follow-up questionnaires, and commits to use the app
7. Owns a smartphone with Android operating system and has regular access to the Internet
8. Provides a postal address and telephone number, and a valid e-mail address
9. Lives in Switzerland or in France

### Participant type(s)
All

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
5293

### Key exclusion criteria
Prior use of the Stop-tabac app for smartphones (self-report)

### Date of first enrolment
10/04/2019

**Date of final enrolment**
25/03/2020

# Locations

**Countries of recruitment**
Switzerland

**Study participating centre**
**ISG - Faculty of Medicine - University of Geneva**
9 chemin des Mines
Campus Biotech
Geneva
Switzerland
1202

# Sponsor information

**Organisation**
University of Geneva

**ROR**
https://ror.org/01m1pv723

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

**Alternative Name(s)**
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

### Location
Switzerland

# Results and Publications

### Individual participant data (IPD) sharing plan
A data management plan was submitted and accepted by the Swiss National Science Foundation, which supports this project. The shared SPSS data file, with participant-level data, will be fully documented, which means that the variable labels and value labels will include the full wording of questions and of response options.
An accompanying README.TXT file will include:
1. An explanation of how and when the data were collected and prepared
2. The names and addresses of the investigators
3. The conditions required to access the data
4. A description of the original study and of the data collection methodology
5. Additional information about how the data were collected, processed and analyzed, giving more technical details than in the publications
6. The SPSS syntax used to transform variables
7. A list of the publications based on these data
The trialists will deposit the participant-level data, with sufficient accompanying metadata and information, on the future repository of Swiss Universities (DLCM project), that will most certainly be available when the study
ends (https://scicore.unibas.ch/projects/dlcm/). If the DLCM project does not materialize, the trialists will archive the data in the ZENODO repository (https://zenodo.org/). The data file will be identified by a DOI. The data will be made available after the publication of the main article describing the study's results. In the final shared data file, the data will be anonymous, and any indication allowing the identification of study participants will be deleted (names, addresses, e-mails, phone numbers). There will be no possibility to track the identity of study participants. As required by Swiss law, the study will be approved by the ethics committee of the canton of Geneva. This approval will include the data collection, storage and sharing procedures. Study participants will be informed that their responses to the questionnaires will be made publicly available in an anonymous format. This will be included in the informed consent form.

### IPD sharing plan summary
Stored in publicly available repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 05/11/2021 | 08/11/2021 | Yes | No |
| Protocol article | protocol | 01/06/2020 | 04/06/2020 | Yes | No |
| Other publications | Secondary analysis | 05/06/2023 | 06/06/2023 | Yes | No |
| Other publications | Secondary analysis | 18/07/2023 | 09/06/2025 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |