# Evaluation of the "Stop Tabac" Android phone application

Submission date	Recruitment status	[X] Prospectively registered
24/06/2015	No longer recruiting	∐ Protocol
Registration date	Overall study status	Statistical analysis plan
02/07/2015	Completed	Results
Last Edited	Condition category	Individual participant data
30/03/2016	Mental and Behavioural Disorders	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Background and study aims

The health issue studied here is stopping smoking (smoking cessation). Self-help methods for smoking cessation can be inexpensive methods that work well and can be made accessible to many people. New technologies can be used as self-help supports. We would like to test how well a new smoking cessation smartphone application called Stop-Tabac works at getting people to kick the habit.

#### Who can participate?

All adult smokers willing to use a phone application can participate to the study.

#### What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (intervention) receive the real smoking cessation smartphone application. Those in group 2 (control) receive a placebo (smartphone application with minimal content on stopping smoking). All participants are asked to complete online questionnaires at the start of the study, 3 months after the study starts and then at 6 months.

## What are the possible benefits and risks of participating?

The benefits of participating in the study is the possibility of the participant receiving the real phone application, and the chance of taking part in a scientific research aimed at assisting smokers to stop smoking. The risks of participating in the study is that a participant may be assigned to the placebo phone application. However, the use of any other kind of smoking cessation aid is allowed during the study.

## Where is the study run from?

Institute of Global Health, University of Geneva (Switzerland)

When is the study starting and how long is it expected to run for? July 2015 to July 2016

## Who is funding the study?

Tobacco Control Fund of the Swiss Federal Office of Public Health

Who is the main contact? Mrs Céline Mavrot celine.mavrot@kpm.unibe.ch

## Contact information

## Type(s)

Scientific

#### Contact name

Mrs Céline Mavrot

#### **ORCID ID**

http://orcid.org/0000-0001-9603-5790

#### Contact details

Schanzeneckstrasse 1 Bern Switzerland 3001

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

#### Scientific Title

Efficacy of a new smoking-cessation phone application: a randomized trial.

## **Study objectives**

13.5% of the phone application users quit smoking after 6 months vs. 11% of the placebo phone application users quit smoking after 6 months

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The ethic board Kantonale Ethikkommission Bern (KEK) declared on 19/02/2015 that this study did not require an approval of the competent ethics commission (the KEK).

## Study design

#### A two-group randomized controlled trial

#### Primary study design

Interventional

## Secondary study design

Randomised controlled trial

#### Study setting(s)

Internet/virtual

## Study type(s)

Prevention

#### Participant information sheet

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

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

Smoking cessation

#### **Interventions**

- 1. Intervention group of the randomized trial: receives the real smoking cessation smartphone application
- 2. Control group of the randomized trial: receives a placebo smoking cessation smartphone application (minimal content)

#### **Intervention Type**

Device

## Primary outcome measure

Primary outcome: smoking/not smoking, measured by self-administrated online questionnaires, completed at baseline, after 3 months and after 6 months.

## Secondary outcome measures

N/A

## Overall study start date

24/06/2015

## Completion date

17/05/2017

# Eligibility

## Key inclusion criteria

- 1. Adults (+18)
- 2. Smokers
- 3. Having approved the information and consent form
- 4. Willing to use the Android phone application

## Participant type(s)

Other

#### Age group

Adult

## Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

6000 (3000 intervention group; 3000 control group)

#### Key exclusion criteria

- 1. Minors (-18)
- 2. Non-smokers
- 3. Not approved the information and consent form
- 4. Not having an Android smartphone

#### Date of first enrolment

17/11/2015

#### Date of final enrolment

17/11/2016

## Locations

#### Countries of recruitment

Switzerland

## Study participating centre Institute of Global Health, University of Geneva

9 Chemin des Mines 1211 Genève 20 Geneva Switzerland 1211

# Sponsor information

## Organisation

Center of Competence for Public Management - University of Berne

## Sponsor details

Schanzeneckstrasse 1 Bern Switzerland 3001

#### Sponsor type

University/education

#### Website

http://www.kpm.unibe.ch/content/index\_eng.html

#### **ROR**

https://ror.org/02k7v4d05

# Funder(s)

## Funder type

Government

#### **Funder Name**

Tobacco Control Fund of the Swiss Federal Office of Public Health

## **Results and Publications**

## Publication and dissemination plan

The authors from Universities Bern and of Geneva have planned to publish the results on the efficacy of the Stop-Tabac smartphone application in a scientific journal specialized in the field of addictions.

## Intention to publish date

17/05/2018

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not expected to be made available