# Evaluation of the efficacy of a mobile application developed for cannabis users to help them reduce or quit their consumption

| Submission date   | Recruitment status No longer recruiting  Overall study status Ongoing  Condition category | <ul> <li>Prospectively registered</li> <li>Protocol</li> <li>Statistical analysis plan</li> <li>Results</li> <li>Individual participant data</li> </ul> |  |  |
|-------------------|---|---|--|--|
| 03/10/2024        |   |   |  |  |
| Registration date |   |   |  |  |
| 25/11/2024        |   |   |  |  |
| Last Edited       |   |   |  |  |
| 05/09/2025        | Mental and Behavioural Disorders  | [X] Record updated in last year   |  |  |

#### Plain English summary of protocol

Background and study aim

Digital interventions offer opportunities for cannabis users willing to stop or reduce their consumption, but who may be reluctant to seek physical help or are far from a specialised health centre. A personalised 5-week e-coaching program has been designed and developed based on an app in association with other services such as helpline, peer forums and chat services. The main aim of this study is to assess the effectiveness of the cannabis app in helping to stop or reduce cannabis use.

#### Who can participate?

People aged 18 years or over who are willing to stop or reduce their current cannabis consumption

#### What does the study involve?

Participants are recruited mainly through the drogues-info-service.fr (DIS) website managed by Santé publique France and randomly allocated to an intervention group or a control group. The intervention group are invited to download the app (available on Google Play and Apple Store). The control group will receive a leaflet with basic information about the harmful effects of cannabis and how to find help. Data will be collected using online questionnaires sent to participants at the start of the study, after the intervention and 3 months later. To evaluate the effectiveness of the intervention, the number of joints smoked in the last 7 days are compared between the two groups at 3 months after the end of the intervention. Secondly, the number of joints smoked in the last 7 days just after the intervention and the number of days with cannabis consumption in the last 7 days at 3 months will also be compared. The level of satisfaction and perceived utility of the app will also be analysed.

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

Participants of the intervention group can continue to use the app beyond the duration of the experiment. Participants in the control group can download the app after answering the last

follow-up questionnaire. Participants who have fully completed the three study questionnaires will receive a gift card worth €20 and access to a random draw allowing five of them to win an additional gift card worth €300.

Where is the study run from?

Santé publique France, the French national public health agency, manages the study. As the experiment involves only the use of a personal smartphone, there is no special or dedicated place to participate.

When is the study starting and how long is it expected to run for? March 2022 to January 2026

Who is funding the study? Santé publique France

Who is the main contact? Emmanuel Lahaie, emmanuel.lahaie@santepubliquefrance.fr

#### Study website

https://www.etudeescal.fr/

# Contact information

#### Type(s)

Public, Scientific, Principal Investigator

#### Contact name

Mr Emmanuel Lahaie

#### **ORCID ID**

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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

Efficacy of a digital intervention to reduce or stop cannabis use: study protocol for a randomized controlled trial (ESCAL)

#### Acronym

ESCAL-protocol

#### Study objectives

This mobile application increase the chance of reducing or quiting the cannabis use of cannabis users willing to reduce or quit their consumption

#### Ethics approval required

Ethics approval not required

#### Ethics approval(s)

In view of the information collected and the type of intervention, this study has been qualified as an evaluation in the field of health outside research involving humans, in accordance with the recommendations of the referal methodology MR-004 of the CNIL (independent administrative authority created by the National Data Protection Act in 1978)

As a research of public interest, the data controller has undertaken to collect only data that is strictly necessary and relevant to the objectives of the research. The protocol has been registered in a public directory held by the Health Data Hub (health-data-hub.fr, number 17990932)

#### Study design

Interventional two-arm 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

See outputs table

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

Problematic cannabis use

#### **Interventions**

Cannabis users are invited to complete an online information and consent questionnaire and for those eligible a first questionnaire about their use (T0). Those who have completed the T0 questionnaire are included and randomised into two groups. Randomization follows the order of arrival of participants. Allocation is done every other time in each group.

Participants in the intervention group receive:

- 1. An invitation (email) to download the app, named "Jeanne" and to use it during the 5-week program of the app
- 2. Invitations to complete two follow-up questionnaires at the end of the program (T1) and 3 months after (T2)

Participants in the control (non-intervention) group receive:

- 1. A PDF leaflet including basic information about the risks of cannabis use
- 2. Invitations to complete two follow-up questionnaires at T1 and 3 months after (T2)

#### **Intervention Type**

Behavioural

#### Primary outcome measure

The number of joints smoked in the last 7 days, measured at 3 months after the end of the intervention (T2)

#### Secondary outcome measures

- 1. The number of joints smoked in the last 7 days, measured just after the intervention (T1)
- 2. The number of days with cannabis consumption in the last 7 days, measured at 3 months (T2)
- 3. The level of satisfaction and perceived utility of the app, measured at T1

#### Overall study start date

12/03/2022

#### Completion date

15/01/2026

# Eligibility

#### Key inclusion criteria

- 1. Age >= 18 years old
- 2. Have used cannabis in the last 7 days
- 3. Willing to reduce or quit cannabis use in the next 15 days
- 4. Have a smartphone connected to the internet
- 5. French speaking

#### Participant type(s)

**Population** 

#### Age group

Adult

#### Lower age limit

#### Upper age limit

99 Years

#### Sex

Both

#### Target number of participants

580

#### Total final enrolment

629

#### Key exclusion criteria

- 1. Not currently following treatment for cannabis addiction
- 2. Not pregnant
- 3. Not recently hospitalized for mental disorders
- 4. Not having used digital or online help to stop or reduce cannabis in the last few months

#### Date of first enrolment

17/10/2024

#### Date of final enrolment

31/08/2025

# Locations

#### Countries of recruitment

France

French Guiana

French Polynesia

French Southern Territories

Saint Martin (French part)

# Study participating centre Santé publique France

12, rue du val d'osne Saint-Maurice France 94415

# Sponsor information

#### Organisation

Santé Publique France

#### Sponsor details

12, rue du Val d'Osne Saint-Maurice France 94415 +33 (0)1 41 79 67 00 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

# **Results and Publications**

#### Publication and dissemination plan

Planned publication in an English-language peer-reviewed journal

#### Intention to publish date

31/12/2026

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Emmanuel Lahaie (emmanuel.lahaie@santepubliquefrance.fr). Anonymized data can be shared with external teams after analysis of the project by Santé publique France and the 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? |
|-------------------------------|--------------------------|--------------|------------|----------------|-----------------|
| Other files                   | Data collection protocol |              | 11/10/2024 | No             | No              |
| Participant information sheet |                          |              | 11/10/2024 | No             | Yes             |