

# ESAS: Electronic study on alcohol among students

<b>Submission date</b> 02/12/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/12/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/02/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Unhealthy alcohol use is a major morbidity and mortality risk factor among students. Electronic screening and brief interventions have the potential to limit drinking and its consequences by reaching large parts of the population that do not necessarily access care. Computer or internet-based interventions targeting unhealthy alcohol use have shown promising results, but efficacy is limited. Smartphones offer an opportunity for interventions with multiple contacts at the user's convenience, which may increase interventions' efficacy. Smartphone applications also allow delivering interventions in context outside of reach of face-to-face or computerized intervention, including in situations in which people are drinking alcohol, for example at parties. Evidence of efficacy of computer or internet-based interventions cannot be extrapolated to smartphone applications: computers and smartphones are used differently, which may change their impact. Research is only starting in this area and efficacy of smartphone applications is largely unknown.

**Aim:** This project proposes a mixed methods approach to develop and test the efficacy of a smartphone application aimed at decreasing unhealthy alcohol use in students.

### Who can participate?

Registered students aged 18 years or older, studying at one of the participating Schools /Universities (French part of Switzerland) who screen positive for unhealthy alcohol use.

### What does the study involve?

Participating in 4 assessments over a 12 months period

Participants may be given access to a smartphone app with prevention material

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

There may be no direct benefit to participants. Potential benefits to participants include the possibility to reduce alcohol consumption and related problems; participants also may benefit from assessments and monitoring of alcohol use. They might take advantage of study participation to think about their behavior and life values and better know themselves.

The risks of serious adverse consequences as a result of study participation are relatively low.

Participants might have concerns about confidentiality of sensitive information reported during the study assessments. The sensitive nature of some of the questions (e.g., alcohol-related) may cause participants discomfort.

Where is the study run from?

Lausanne University Hospital and University of Lausanne, Switzerland

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

April 2020 to June 2022

Who is funding the study?

Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung (Swiss National Science Foundation)

Who is the main contact?

Dr Nicolas Bertholet

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

Swiss National Science Foundation 176295

# Study information

## Scientific Title

Smartphone-based secondary prevention intervention for students with unhealthy alcohol use: qualitative study and randomized controlled trial

## Acronym

ESAS

## Study objectives

Participants in the intervention group (experimental condition: secondary prevention intervention delivered via a smartphone application) will report a smaller volume of drinking (measured with the mean number of drinks per week consumed over the past 30 days) at the 6-month follow-up compared to participants in the control group (receiving electronic assessment only).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 25/05/2018, Commission cantonale (VD) d'éthique de la recherche sur l'être humain (CER-VD) (Ethics committee of the Canton de Vaud, Avenue de Chailly 23, 1012 Lausanne, Switzerland; +41 21 316 18 30; secretariat.cer@vd.ch), ref: 2018-00560

## Study design

Interventional randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Prevention

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

Unhealthy alcohol use

## Interventions

Qualitative study: a member of the target population (i.e. fulfilling the randomized trial inclusion criteria) will be recruited to download and test a prototype of the smartphone-based intervention. After providing written informed consent, participants (n=20) are taking part in two rounds of qualitative assessments (individual semi-structured interviews). The smartphone-based intervention is modified after each round. An interview grid was developed for the project. All interviews are audio-recorded and transcribed verbatim. A conventional content analysis is conducted.

Phase I, development of the smartphone application and qualitative assessment: the piloted smartphone application will be further developed, notably to send messages to participants following pre-specified scenarios based on application usage. Modifications will be done in an

iterative process. Two rounds of qualitative assessments (individual semi-structured interviews and focus group) will be conducted among members of the study population. Each round will lead to modifications in the smartphone application.

Phase II, randomized controlled trial: the application's efficacy will be tested in a two parallel-group randomized controlled trial with a 1:1 allocation ratio with follow-up assessments at 3, 6 and 12 months.

Control (assessment only)

Intervention (assessment + smartphone application).

The entire randomized trial will be conducted electronically. Randomization is embedded within study website with full concealment of allocation. Electronic assessments at follow-up (3, 6, 12 months post baseline)

Intervention: providing access to a secondary prevention intervention targeting unhealthy alcohol use, delivered via a smartphone application

### **Intervention Type**

Other

### **Primary outcome(s)**

Mean number of drinks per week over the past 30 days (electronic self-report), measured at 6 months

### **Key secondary outcome(s)**

All electronic self-report, measured at 6 months:

1. Number of heavy drinking days over the past 30 days
2. Additional outcomes will be: maximum number of drinks on any day over the past 30 days, alcohol related consequences (measured with the Short Inventory of Problems (SIP-2R), and academic performance

### **Completion date**

12/06/2022

## **Eligibility**

### **Key inclusion criteria**

1. Registered student at one of the participating Schools/Universities (French part of Switzerland)
2. Age 18 years and over
3. Positive screen for unhealthy alcohol use
4. Smartphone ownership
5. Willingness to complete follow-up assessments

### **Participant type(s)**

Learner/student

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

1770

**Key exclusion criteria**

1. Students who participated in the development of the smartphone application

**Date of first enrolment**

26/04/2021

**Date of final enrolment**

28/04/2021

## **Locations**

**Countries of recruitment**

Switzerland

**Study participating centre**

Lausanne University Hospital and University of Lausanne

Addiction Medicine

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## **Sponsor information**

**Organisation**

Lausanne University Hospital

**ROR**

<https://ror.org/05a353079>

## **Funder(s)**

**Funder type**

Government

**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**

The current data sharing plans for this study are unknown and will be available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		16/08/2023	17/08/2023	Yes	No
<a href="#">Protocol article</a>	protocol	17/02/2020	24/02/2020	Yes	No
<a href="#">Other publications</a>	qualitative outcome data on the app development process	07/03/2023	08/03/2023	Yes	No
<a href="#">Other publications</a>	Secondary mediation analysis	06/02/2025	07/02/2025	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes