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ESAS: Electronic study on alcohol among students

Submission date	Recruitment status	[X] Prospectively registered
02/12/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/12/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/02/2025	Mental and Behavioural Disorders	

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?
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Study website
http://p3.snf.ch/Project-176295#

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
Swiss National Science Fondation 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

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

Secondary outcome measures
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

Overall study start date
30/03/2017

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,696

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
Bugnon 23A
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Sponsor information

Organisation
Lausanne University Hospital

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Sponsor type
Hospital/treatment centre

Website
http://www.chuv.ch

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, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Results will be presented at international conference and published in peer reviewed journals.

Intention to publish date
31/08/2023

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?
Protocol article	protocol	17/02/2020	24/02/2020	Yes	No
Other publications	qualitative outcome data on the app development process	07/03/2023	08/03/2023	Yes	No
Results article		16/08/2023	17/08/2023	Yes	No
Other publications	Secondary mediation analysis	06/02/2025	07/02/2025	Yes	No