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Swiss Study on Young People and Alcohol

Submission date
12/06/2012

Recruitment status
No longer recruiting

Registration date
20/07/2012

Overall study status
Completed

Last Edited
18/12/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Unhealthy alcohol use (alcohol consumption that is associated with varying degrees of risk to health, such as injury, trauma, physical, psychological or social harm) is a leading cause of illness and death among young adults. It is therefore crucial to develop preventive interventions targeting unhealthy alcohol use. Face-to-face brief interventions targeting alcohol use are considered effective in primary care settings, but young individuals tend to have limited contacts with the health care system and are therefore unlikely to receive any intervention. As a result, electronic brief interventions have been developed that can reach a broad population at a relatively low cost and potentially impact the public health system. Electronic screening and brief interventions (E-SBI) targeting alcohol use are effective among college students, but more evidence is needed in order to evaluate E-SBI designed for young individuals in other settings. There is also a lack of knowledge about the primary prevention effects of these interventions on, for example, moderate drinkers. The aim of this study is to evaluate the effectiveness of a proactive E-SBI providing personalized feedback and information on alcohol use and its consequences among young men in the general population, to determine how young men will use E-SBI to obtain information on alcohol use and its consequences, and to evaluate how young men perceive the use of Internet to deliver preventive interventions. We think that E-SBI will decrease later alcohol use and related consequences among individuals with unhealthy alcohol use, and will prevent the increase of alcohol use among individuals without unhealthy alcohol use.

Who can participate?
The study participants will come from a population-based sample of 20-year-old men recruited from among participants in the Cohort Study on Substance Use Risk Factors (C-SURF).

What does the study involve?
Participants will be randomly allocated to either receive electronic personalized feedback (intervention group) or to not receive feedback (control group), and will be followed up at 1 month and at 6 months. The electronic personalized feedback includes self-assessment of current alcohol use and consequences, personalized feedback on alcohol use, and general information on alcohol use and its consequences (i.e., factsheets). Participants who report unhealthy alcohol use are encouraged to modify their drinking habits, and are presented with the rationale for risks associated with their current use of alcohol. Participants have the opportunity to print their personalized feedback form, and are able to access a section

containing general information on alcohol use and its consequences. Participants in the control group complete the same baseline assessment as do members of the intervention group, but neither receive personalized feedback nor have access to the general information section on the website. The approximate time to complete the baseline assessment is three minutes. All participants are asked if they think that the Internet is a suitable option for providing personalized information about substance use.

What are the possible benefits and risks of participating?
There are several benefits from this study. The direct benefits include improvement in drinking habits if E-SBI proves to be effective, and the assessments and other information that participants will receive as feedback might give them a heightened awareness of their drinking habits and encourage them to drink less alcohol. The major risk in this research is breach of confidentiality, but great effort have been made to minimize that risk as much as possible. Electronic interventions have no reported or known side effects. The possible risk of harm to participants caused by this study is limited; therefore the potential benefits outweigh any potential risks.

Where is the study run from?
Lausanne University Hospital, Lausanne, Switzerland.

When is the study starting and how long is it expected to run for?
The recruitment starts in June 2012 and will last until July 2014.

Who is funding the study?
The Swiss National Science Foundation (Switzerland).

Who is the main contact?
Nicolas Bertholet
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Contact information

Type(s)
Scientific

Contact name
Dr Nicolas Bertholet

Contact details
Alcohol Treatment Center
Lausanne University Hospital
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1011

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
135538 Swiss National Science Foundation

Study information

Scientific Title
Electronic alcohol screening and brief intervention (E-SBI) for young adults:a randomized controlled trial

Acronym
SSYPA

Study objectives
It is hypothesized that E-SBI will decrease later alcohol use and related consequences among individuals with unhealthy alcohol use and will prevent the increase of alcohol use among individuals without unhealthy alcohol use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics for the Research on Human Beings (Cantonal commission) 22 August 2011 ref: 260/2011

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Alcohol use

Interventions

Web based brief intervention and information on alcohol use and its consequences (primary and secondary prevention intervention dependending on alcohol use level, duration: approx. 10 minutes, web-based)

Comparator: No intervention

Follow-up at 1 and 6 month

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Self reported alcohol use:
1. Weekly alcohol consumption (number of drinks per week, where one drink contains 10g of ethanol)
2. Monthly frequency of Risky Single Occasion Drinking episodes (RSOD corresponding to 6 or more drinks per occasion)

Secondary outcome measures
1. Number of consequences due to alcohol
1.1. Was injured or injured someone else
1.2. Had a hangover
1.3. Missed a class or work
1.4. Performed poorly at work
1.5. Did something that was later regretted
1.6. Had a blackout
1.7. Got into an argument or fight with friends
1.8. Had unplanned sex
1.9. Had unprotected sex
1.10. Damaged property
1.11. Had problems with the police
1.12. Received medical treatment
1.13. Observed negative impact on physical health and observed negative impact on mental health
2. Computed Blood Alcohol Concentration (BAC), based on maximum reported alcohol
3. Presence of unhealthy alcohol use (¡Ý 21 drinks per week or at least one RSOD episode per month)
4. Use of the website (number of visits on information pages)

Overall study start date
01/07/2012

Completion date
31/07/2014

Eligibility

Key inclusion criteria

1. Study participants are recruited among partcipants to the Cohort Study on Substance Use Risk Factors (C-SURF)
2. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1200

Total final enrolment
737

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/07/2012

Date of final enrolment
31/07/2014

Locations

Countries of recruitment
Switzerland

Study participating centre
Alcohol Treatment Center
Lausanne
Switzerland
1011

Sponsor information

Organisation
Swiss National Science Foundation (Switzerland)

Sponsor details

Wildhainweg 3
PO Box 8232
Berne
Switzerland
3001

Sponsor type
Government

Website
http://www.snf.ch/E/Pages/default.aspx

ROR
https://ror.org/00yjd3n13

Funder(s)

Funder type
Government

Funder Name
Swiss National Science Foundation (Switzerland) ref: 135538

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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/12/2015		Yes	No
Results article	results	01/08/2018	18/12/2019	Yes	No