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Prevention of risky drinking among university students. A study of the effectiveness of a mail-based computerized screening and personalised feedback in three universities in Sweden the AMADEUS 2 study

Submission date
04/03/2013

Recruitment status
No longer recruiting

Registration date
25/04/2013

Overall study status
Completed

Last Edited
18/12/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Going to university is associated with increased levels of heavy drinking. Alcohol is often used to promote social integration despite the potential negative consequences of excessive drinking among students. Therefore, in most countries around the world the number of students with risky drinking is high - often above 50 % of the total student population. College and university students constitute a large and important proportion of the future labour force. Already at an early stage of a professional career it is fundamentally important to have sensible alcohol habits in order to prevent future negative alcohol-related consequences. This calls for value for money treatments in order to reach the maximum number of students starting university each year. The objective of the study is to assess how well a fully automated email-based internet alcohol intervention works.

Who can participate?
Eligible participants are all term 2,4 and 6 students whose drinking habits are hazardous or harmful in nine colleges and universities in Sweden identified by a single screening question.

What does the study involve?
The students get an invitation to participate in the study via an e-mail with a single question screening for risky drinking. Risky drinkers are then randomly allocated to an Intervention group which will have access to the internet alcohol intervention or a control group that will have access to the intervention after 2 months (at the time of a follow-up of the intervention group).

What are the possible benefits and risks of participating?
The possible benefits from participating for the individuals are a personalized feedback on their alcohol consumption with recommendations about sensible drinking. There are no known side effects.

Where is the study run from?
The study is carried out by researchers at Linköping University, Sweden, using students from nine universities in Sweden.

When is the study starting and how long is it expected to run for?
The study started in February 2013 and will end in June 2013. The recruitment period will be for 3 weeks. A follow-up of all participants will be done after 2 months.

Who is funding the study?
The study is funded by The Swedish Council For Working Life and Social Research (FAS, in Swedish).

Who is the main contact?
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Study website
http://demo.livsstilstest.nu

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AMADEUS 2 version 1

Study information

Scientific Title
Prevention of risky drinking among university students. A RCT study of the effectiveness of a mail-based computerized screening and personalised feedback in three universities in Sweden the AMADEUS 2 study

Acronym
AMADEUS 2 study

Study objectives
The study aims to evaluate the effectiveness of a mail-based Internet alcohol intervention (eSBI) offered to non treatment seekers among university students, The study will randomise risky drinkers to an intervention group or a waiting list group that first will have access to the Intervention after 2 months.

Current hypothesis as of 02/07/2013:
The hypothesis is that the intervention group will have a lower total weekly alcohol consumption than the waiting list group at the time of follow-up.

Previous hypothesis:
The hypothesis is that the Intervention group will have a 5-10% lower total weekly alcohol consumption than the waiting list group at the time of follow-up.

Added 02/07/2013:
55,000 students to be invited. It is desirable that this study is as large as possible. For indicative purposes to detect an effect size of 0.1 standard deviations between the two groups with 5% significance level and 80% power, we required 1,600 individuals analysed per group. Assuming a follow-up rate of 50%, we should aim to recruit 3,200 individuals per group i.e. 6,400 in total. We had no data on the number of screen positives who may be willing to participate in this trial and assumed approximately 70% would do so, meaning that we would need to identify approximately 8,000 hazardous and harmful drinkers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee in Linköping Sweden, 20/02/2013, ref: Dnr 2013/46-31

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Prevention of risky drinking

Interventions
Intervention group and a waiting list group.

The study is based on a mail-based computerized alcohol intervention (eSBI) that has been developed by the Lifestyle Intervention Research group (LIR group) at Linköping University. In short, the students receives a mail from the student health care service with a short welcome greeting followed by an invitation to perform a computerized alcohol test by clicking on a hyperlink. Two reminders are sent with a week apart to those who have not answered and thereafter the link is closed. The link can only be used once in order to ensure that each student only performs the test once. The test includes questions about average consumption day by day in a typical week during the last 2 months, frequency of binge drinking, highest blood alcohol concentration (BAC) the last two months (calculated by the computer based upon the students input), experienced negative consequences related to alcohol, views upon how much other students and peers drink, and questions about motivation to change.

The student then gets immediate feedback by computer consisting of three statements summarizing their weekly consumption, their frequency of heavy episodic drinking and their highest blood alcohol concentration during the last three months, comparing the respondents' drinking patterns against the safe drinking limits established by the Swedish Institute for Public Health. After this follows a comprehensive normative feedback with information describing participants' alcohol use compared to peers at the university, and, if applicable, personalized advice concerning the need for reducing any unhealthy levels or pattern of consumption. The feedback can be printed out by the student.

Intervention Type
Behavioural

Primary outcome measure
Total weekly alcohol consumption.

Secondary outcome measures
Current secondary outcome measures as of 02/07/2012:
1. Proportion drinking above official safe drinking limits
2. Frequency of drinking (number of days per week)
3. Quantity of drinks per drinking day
4. Frequency of heavy episodic drinking as defined in the screening question
5. Highest estimated blood alcohol concentration (eBAC)
6. Stage of change

Previous secondary outcome measures:
1. The frequency of drinking (number of days per week)
2. Quantity of drinks per
3. Drinking day

4. Frequency of heavy episodic drinking
5. Highest estimated blood alcohol concentration (eBAC)

Overall study start date
27/02/2013

Completion date
15/06/2013

Eligibility

Key inclusion criteria
All term 2, 4 and 6 students (both sexes and between 18 and 30 years of age) at nine colleges and universities in Sweden were invited to participate by an email.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
55,000 students

Total final enrolment
1605

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
27/02/2013

Date of final enrolment
15/06/2013

Locations

Countries of recruitment
Sweden

Study participating centre

Linköpings Universitet
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Sponsor information

Organisation
Swedish Council for Working Life and Social Research (Sweden)

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Swedish Council For Working Life and Social Research (Sweden) grant number 2010-0024.

Alternative Name(s)
Swedish Council for Working Life and Social Research, FAS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Sweden

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?
Protocol article	protocol	10/10/2013		Yes	No
Results article	results	09/07/2015		Yes	No
Other publications	re-analysis using a Bayesian framework	17/12/2019	18/12/2019	Yes	No