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Alcohol eMail Assessment & feedback study Dismantling Effectiveness for University Students: the AMADEUS-1 trial

Submission date
13/10/2011

Recruitment status
No longer recruiting

Registration date
04/11/2011

Overall study status
Completed

Last Edited
08/11/2019

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
Because alcohol causes huge health problems for society in order to prevent and reduce problems we need to help people think about their drinking. This can be done online, asking people to complete a few questions and giving brief feedback and advice where it may be needed. This study aims to find out whether a brief online intervention works, and whether it is necessary to receive feedback or whether simply answering questions helps people to think about their drinking and to change it.

Who can participate?
Students from two universities in Sweden.

What does the study involve?
Participants are randomly allocated into three groups. The first group receive an e-mail asking them to participate in a short 9-question survey about alcohol habits. After completing the questionnaire they immediately receive feedback about their alcohol consumption, comparing their drinking patterns against the safe drinking limits established by the Swedish Institute for Public Health. After this follows feedback describing their alcohol use compared to their peers in Swedish universities and, if applicable, personalised advice concerning the importance of reducing unhealthy levels or patterns of drinking. The feedback can be printed out by the student. The second group are not contacted at all until the end of the study. The third group complete the questionnaire without getting feedback. After 3 months all three groups receive an email asking them to participate in a seemingly unrelated general health survey about students' lifestyle habits with no reference to the previous surveys. All students at this time have an opportunity to receive personalised feedback.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Two universities in Sweden.

When is the study starting and how long is it expected to run for?
September to December 2011.

Who is funding the study?
Swedish Council for Working Life and Social Research (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Alcohol eMail Assessment & feedback study Dismantling Effectiveness for University Students: the AMADEUS-1 trial

Acronym
AMADEUS-1

Study objectives
Evaluate the effectiveness of electronic screening and brief intervention (e-SBI), employing an randomised controlled trial (RCT) design that takes account of baseline assessment reactivity (and other possible effects of the research process) due to the similarity between the intervention and assessment content. The hypothesis is that the assessment has an impact on drinking behaviour but to a lesser extent that the intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Regional Ethical Committe in Linköping, Sweden, 12/10/2010, ref: 2010/291-31

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Risky alcohol consumption

Interventions
Intervention delivery begins with receipt of an e-mail with a hyperlink to a computerised alcohol intervention. The mail is send from the local student health care asking them to participate in a short 9 question survey concerning alcohol habits. They will be informed that the survey is part of the university´s work with alcohol in general. After having completed a 9 item questionnaire the intervention Group feedback immediately upon completion of the assessment consisting of three statements summarising their weekly consumption, their frequency of heavy episodic drinking and their highest blood alcohol concentration during the last four weeks, comparing drinking patterns against the safe drinking limits established by the Swedish Institute for Public Health. After this follows comprehensive normative feedback with information describing participants' alcohol use compared to their peers in Swedish universities, and, if applicable, personalised advice concerning the importance of reducing any unhealthy levels or pattern of consumption. The feedback can be printed out by the student. A demonstration version can be viewed of the assessment and feedback intervention can be viewed at demo.livsstilstest.nu.

The present study is designed in such a manner that the control group is as non contaminated as possible from the possible effects of research participation.Two kind of control groups will therefore be included in the study
1. A no contact group that do not know they will be asked to complete a seemingly unrelated general health survey, including alcohol questions, after 3 months
2. An assessment only group that complete the baseline questionnaire without getting a feedback who also do not know they will be asked to complete a seemingly unrelated general health survey, including alcohol questions, after 3 month.

After 3 month all students in all three groups will receive a mail from the research group asking them to participate in a seemingly unrelated general health survey about students lifestyle habits with no reference to the previous survey 3 month earlier. This is done in order minimise a Hawthorne effect in the assessment group and the assessment and feedback group i.e. being aware that the results will be compared with the first survey. The appearance of the two surveys, as well as their source, will be different from each other to protect against this possibility. All students will at this time receive a personalised feedback opportunity directly on the screen of their computer and have the possibility to print it out. The students will also automatically receive a mail with their feedback so they can read the feedback at a later stage.

Intervention Type
Behavioural

Primary outcome(s)
1. Reduced average alcohol consumption
2. Reduced frequency of heavy episodic drinking
3. Reduced maximal drinking at one occasion
Measured at baseline before they get a written feedback and after 3 months before another written feedback

Key secondary outcome(s))
Reduction in proportion of students with risky drinking. Measured at baseline before they get a written feedback and after 3 months before another written feedback.

Completion date
31/12/2011

Eligibility

Key inclusion criteria
All university students at term 1, 3 and 5 in two universities in Sweden

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/09/2011

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Sweden

Study participating centre
Linköping University
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581 83

Sponsor information

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

ROR
https://ror.org/02d290r06

Funder(s)

Funder type
Government

Funder Name
Swedish Council for Working Life and Social Research (Sweden) ref: 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

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	01/11/2013		Yes	No
Protocol article	protocol	06/07/2012		Yes	No
Other publications	reanalysis	07/11/2019	08/11/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes