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# An evaluation of an SMS-based support service targeting alcohol consumption among university students

**Submission date**
31/08/2016

**Recruitment status**
No longer recruiting

**Registration date**
27/09/2016

**Overall study status**
Completed

**Last Edited**
12/07/2018

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims
Although the awareness of the health risks associated with alcohol, heavy drinking among students is still a problem and a social norm at universities. A growing number of research show several benefits with SMS-based support such as cost-effectiveness, accessibility and require limited effort by users. This study aims to evaluate a newly developed SMS-based service targeting excessive drinking among university and college students in Sweden.

Who can participate?
University students who drink at least 4 standard drinks (women) or 5 standard drinks (men) at least two twice a month, are willing to attempt to reduce their drinking, own a mobile phone and are willing to give their mobile phone number.

What does the study involve?
The students receive an invitation via e-mail to take part in the study. Students that meet the inclusion criteria will then be randomly allocated to one of two groups. Those in the first group are immediately given access to the SMS-based service. This involves receiving a total of 62 messages of six weeks and include facts about the negative effects of alcohol and tips on how to drink less. Participants in the second group recieve stanadard care (access to recommended websites to help lower alcohol consumption) for three months. At the start of the study and after three months, participants in both groups complete a number of questionnaires in order to assess their drinking. After this, participants in the second group are given access to the SMS-based service.

What are the possible benefits and risks of participating?
Participants benefit from receiving support which could help them to reduce their alcohol consumption. There are no notable risks involved with participating in this study.

The possible benefits from taking part for participants are to receive support in their attempt to reduce their drinking. There are no known side effects.

Where is the study run from?
Linköping University (Sweden)

When is the study starting and how long is it expected to run for?
October 2016 to January 2017

Who is funding the study?
The Public Health Agency of Sweden (Sweden)

Who is the main contact?
Dr Ulrika Mussener

# Contact information

### Type(s)
Scientific

### Contact name
Dr Ulrika Müssener

### ORCID ID
http://orcid.org/0000-0001-5173-5419

### Contact details
Linköping University
Faculty of Health Sciences
Linköping
Sweden
58183

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
AMADEUS SMS

# Study information

### Scientific Title
SMS-based intervention targeting alcohol consumption among university students: a randomized controlled trial

### Study objectives

Primary hypothesis:
Participants in the intervention group will report significantly lower total weekly alcohol consumption at follow-up compare to participants in the control group.

Secondary hypothesis:
The intervention group will report significantly lower eBAC, lower frequency of heavy episodic drinking and number of negative consequences due to excessive drinking compared to the control group.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Central Ethical Review Board, Linköping, 12/03/2016, ref: 2016/134-31 and 2016/279-32

## Study design
Two-arm 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 contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Prevention of risky drinking

## Interventions
Participants will be randomized to the intervention (group 1) or treatment as usual (group 2). Each participant is allocated a number 1 or 2 with equal probabilities using Java's built in random number generator (java. util.Random). Randomization is thus fully computerized, does not employ any strata or blocks, and is not possible to subvert, as this and all subsequent study processes are fully automated.

Intervention group: The intervention consist of a 6-weeks automated SMS-based program with a total of 62 messages. The intervention was developed using formative methods including focus groups with students, expert panel with students and professionals. The number of messages in the program vary each week with higher frequency of messages (nine) at the beginning of the program and less frequent at the end of the program (five). Messages are sent seven days a

week at various times around midday, late afternoon or early evening. SMS messages include e. g. facts about negative consequences of alcohol, tips on behavior change strategies and activities such as saying no to alcohol.

Control group: Participants will be offered conventional care. At the moment, common practice at the Student Health Centre (SHC) is to recommend students two different websites where they can estimate their alcohol consumption, get feedback on their drinking levels and more information on health consequences of drinking. Guidance such as this is currently distributed to students via e-mail from the SHCs. Participants in the control group will be informed via e-mail that they have been allocated to the control group and will gain access to the SMS-based support in about four months. This e-mail will also include tips on websites typically used by the SHCs. Besides this no prompts or reminders about the websites will be performed during the study.

Follow-up will be carried out 3 months after the initial invitation to the study. All participants will be sent an e-mail invitation including a link to a follow-up questionnaire aiming to investigate the primary and secondary outcomes. Two reminders, 1 week apart, will be sent to non-responders, also via e-mail. In addition, participants who still do not respond, will receive an SMS every second day for 6 days (that is 3 additional reminders) These SMS will only include a single question investigating the primary outcome (weekly consumption). Finally, those not responding to the SMS will be contacted via telephone (maximum of 10 calls). Again, only the primary outcome will be investigated. The follow-up questionnaire will include 4 questions investigating the primary and secondary outcomes:
1. Total weekly alcohol consumption during a typical week
2. Heavy episodic drinking during the last month
3. Estimated blood alcohol concentration during the last month
4. Negative consequences caused by drinking alcohol during the last month

### Intervention Type
Behavioural

### Primary outcome measure
Total weekly alcohol consumption is measured using AUDIT-C item at baseline and 3 months

### Secondary outcome measures
1. Frequency of heavy episodic drinking is measured using AUDIT-C item at baseline and 3 months
2. Highest estimated blood alcohol concentration (eBAC) is measured using AUDIT-C item at baseline and 3 months
3. The number of negative consequences due to excessive drinking is measured using AUDIT-C item at baseline and 3 months
4. Perceptions of the intervention and taking part in the study is measured using a specially designed questionnaire at 3 months

### Overall study start date
04/01/2016

### Completion date
23/01/2017

## Eligibility

### Key inclusion criteria
1. Both men and women
2. University students that drink at least 4 standard drinks (women) or 5 standard drinks.(men) on at least two occasions a month
3. University students who are willing to attempt to reduce their alcohol consumption
4. University students who have ownership of a mobile phone
5. University students who and are willing to disclose their mobile phone number

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Sex
Both

### Target number of participants
200,000

### Key exclusion criteria
Not meeting inclusion criteria

### Date of first enrolment
10/10/2016

### Date of final enrolment
30/10/2016

## Locations

### Countries of recruitment
Sweden

### Study participating centre
**Linköping University**
Linköping
Sweden
58183

## Sponsor information

### Organisation
Linköping University

### Sponsor details
Faculty of Health Sciences
Department of Medicine and Health Sciences
Division of Community Medicine
Linköping
Sweden
58183

### Sponsor type
University/education

### Website
www.liu.se

### ROR
https://ror.org/05ynxx418

## Funder(s)

### Funder type
Government

### Funder Name
Folkhälsomyndigheten

### Alternative Name(s)
Public Health Agency of Sweden

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
Sweden

## Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

### Intention to publish date
30/11/2017

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 04/04/2017 | | Yes | No |
| Results article | results | 25/06/2018 | | Yes | No |
| Results article | results | 10/07/2018 | | Yes | No |