

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

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Registration date 27/09/2016	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 12/07/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 receive standard 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
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Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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

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?
Results article	results	25/06/2018		Yes	No
Results article	results	10/07/2018		Yes	No
Protocol article	protocol	04/04/2017		Yes	No