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Reducing risky drinking in the general population of Sweden using an interactive mHealth intervention

Submission date
24/10/2018

Recruitment status
No longer recruiting

Registration date
06/12/2018

Overall study status
Completed

Last Edited
13/02/2025

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
Early initiatives to use electronic health (eHealth) interventions to change alcohol consumption behaviour investigated electronic screening and brief interventions involving normative feedback (eSBI). Commonly, individuals engaging with this type of intervention respond to a series of questions, after which a summary of their alcohol habits is presented, and feedback is given with respect to recommended drinking levels, alongside some advice on behaviour change. The available evidence for eSBIs' effect on alcohol consumption suggests that there exists a positive albeit small reduction in the short term. In attempts to increase the effect and make the benefits continue for longer, it has been suggested that multiple sessions of eSBI should be offered to participants, requiring them to revisit a website several times. However, retention has been problematically low for these types of interventions. With the advent of mobile technology, it is now possible to deliver interventions more ecologically, allowing interventions to be a part of individuals' everyday life. For instance, it is possible to remind participants of their decisions to reduce their alcohol consumption just before the weekend, or ask them to reflect on their consumption on a Sunday evening. Such approaches appear promising from studies of mobile health (mHealth) interventions for behaviour change more widely. The development of mHealth interventions targeting harmful alcohol consumption is still in its infancy, and there is much that is not known with respect to increasing the effect. Interventions that use SMS (short message service) messages to deliver textual content to individuals trying to quit smoking have been widely successful, and the evidence is strongly in favour of such interventions. However, for alcohol the evidence for this type of intervention is less well developed. Trials testing the effectiveness of SMS-based interventions targeting alcohol consumption among young adults have been underpowered and suffered from follow-up attrition, thus while some of these trials have reported small benefits of the interventions, no strong evidence is yet available. The use of smartphone applications for alcohol reduction has also been investigated, but no strong evidence has yet been found. Furthermore, smartphone applications that do not contain any type of reminder facility suffer from similar retention issues as do multiple session eSBIs. For these reasons this study is testing a new intervention that retains the brevity of single session eSBIs, yet also extends the intervention over time using mobile technology.

Who can participate?
People aged 18 or older who are classified as a risky drinker according to Swedish guidelines

What does the study involve?
Participants are randomly allocated to one of two different means of presenting the trial procedure when asking for informed consent (Consent-1 and Consent-2). The information before informed consent is the same for Consent-1 and Consent-2, but Consent-1 participants have all the information available on the same screen, while Consent-2 participants have to click on links to access more information. It is not currently known which method of presenting the information encourages participants to actually read before leaving informed consent. Participants leaving informed consent and completing the questionnaire are randomly allocated to either the Intervention group or the Control group. For the Intervention group the main component of the intervention is an SMS message sent to the participant's mobile phone each week. The SMS message contains a link to a dashboard made available on the participant's mobile phone. The dashboard allows participants to explore their current alcohol consumption, set goals and monitor progress, create plans, learn skills and learn about the risks involved with alcohol consumption. The dashboard also works as a simulation device, allowing participants to enter different levels of consumption and interactively seeing health risks change, e.g. reducing the number of heavy drinking episodes leads to fewer injuries and reduced risk of premature death. As additional support, participants receive SMS messages throughout the week that contain motivational and reinforcing information to help them reduce their alcohol consumption. The control group are randomly allocated further into two groups (Info-1 and Info-2). Both Info-1 and Info-2 receive a single SMS message with basic health information regarding the short and long term effects of alcohol consumption. Two very brief types of information are compared; one which emphasises possible complexities associated with the short and long term effects of alcohol (such as is widely available from alcohol industry sources, Info-1) and another which provides a clear and straightforward public health messaging style (whilst being appropriately evidence informed, Info-2). Both are delivered in a single SMS and include the same link to www.iq.se to access further information. The intervention does not have a specific treatment period, participants can use the tool for as long as they like. However, outcomes are measured at 1, 2 and 4 months later. Access to the intervention is then given to the control group.

What are the possible benefits and risks of participating?
Participating in the trial allows participants to access a new tool that aims to reduce alcohol consumption among risky drinkers. Access is given either immediately after signing up to the trial or after a 4-month period. There is however nothing hindering participants to seek help elsewhere, thus there is no disadvantage to the group that waits for 4 months, as the intervention itself has not been proven to be effective. It cannot be said that the intervention group has been given an advantage, and since there is no strong evidence yet of mHealth interventions' effect on alcohol consumption, the intervention group might be the disadvantaged group as there is a risk that they will trust the tool rather than seeking help elsewhere. The tool is non-invasive and can be turned off at any time - participants are not forced to use it for any set amount of time. It is believed that any increased risk brought on by participating in the trial does not outweigh the benefits of the trial outcomes.

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

When is the study starting and how long is it expected to run for?
October 2017 to December 2020

Who is funding the study?
Linköping University (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Reducing risky drinking in the general population of Sweden using an interactive mHealth intervention

Acronym
TOPHAT 4.0

Study objectives
For an explanation of the different groups, please see Interventions.
1. Alcohol consumption will differ between Intervention and Control groups, with the

Intervention group drinking less than Control at two and four months after randomisation. The two month interval will be primary
2. Confidence, importance and know-how at one-month follow-up will mediate the effects of the intervention on drinking outcomes at two-month follow-up. The same measures at two-month follow-up will mediate the effect on drinking outcomes at four-month follow-up
3. Enrollment rates will differ between groups Consent-1 and Consent-2
4. Accurate recall of study parameters will differ between groups Consent-1 and Consent-2
5. Rates of accessing further information will differ between groups Info-1 and Info-2

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethics Board of Linköping (approval number 2018/417-31): 06/11/2018

Study design
Two-arm parallel group randomised controlled trial with three nested sub-studies

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

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
Risky alcohol consumption among the general population of Sweden

Interventions
In all cases, randomisation will be fully computerised, will not employ any strata or blocks, and will not be possible to subvert as all subsequent study processes are fully automated.

Individuals will be randomised to one of two different means of presenting the trial procedure when asking for informed consent (Consent-1 and Consent-2). The information prior to informed consent will be the same for Consent-1 and Consent-2, however Consent-1 will have all the information available on the same screen, while Consent-2 will have to click on links to access more information. It is not currently known which method of presenting the information encourages participants to actually read prior to leaving informed consent.

Participants leaving informed consent and completing the baseline questionnaire will be randomized to group Intervention or Control.

Group Intervention: The main component of the intervention will be a SMS message sent to a participant's mobile phone each week. The SMS message will contain a hyperlink to a dashboard made available on the participant's mobile phone. The dashboard will allow participants to explore their current consumption, set goals and monitor progress, create plans, learn skills and learn about the risks involved with alcohol consumption. The dashboard will also work as a simulation device, allowing participants to enter different levels of consumption and interactively seeing health risks change, e.g. reducing the number of heavy drinking episodes leads to fewer injuries and reduced risk of premature death etc. As additional support, participants will receive SMS messages throughout the week that contain motivational and reinforcing information to help them reduce their consumption.

Group Control: The control group will be randomised further into two groups (Info-1 and Info-2). Both Info-1 and Info-2 will receive a single SMS message with basic health information regarding short and long term effects of alcohol consumption. In this study we incorporate a contrast between two very brief types of information; one which emphasises possible complexities associated with the short and long term effects of alcohol (such as is widely available from alcohol industry sources, Info-1) and another which provides a clear and straightforward public health messaging style (whilst being appropriately evidence informed, Info-2). Each are delivered in a single SMS and include the same link to www.iq.se access further information.

The intervention does not have a specific treatment period, participants can use the tool for as long as they like. However, for the sake of the trial mediator outcomes will be measured at 1 month after randomisation, and all other outcomes at 2 and 4 months after randomisation. Access to the intervention will then be given to the control group.

Intervention Type
Behavioural

Primary outcome measure
Hypothesis 1 and 2: Total weekly alcohol consumption and frequency of heavy episodic drinking, measured by self-reported at baseline and at 2 and 4 months after randomisation: Total weekly alcohol consumption: How many standard units of alcohol did you consume last week? (numerical measure); Frequency of heavy episodic drinking: How often, during the past month, have you consumed four/five (female/male) or more standard units on one occasion? (numerical measure)
Hypothesis 3 and 4: Enrolment rates from each study condition (Consent-1 and Consent-2) measured after the last participant has been randomised (i.e. at the latest at the end of the recruitment period); and recall of trial procedures measured through a series of questions at 2 months
Hypothesis 5: Rates of additional information being requested by pressing on the supplied hyperlink for the control setting, measured 4 months after the last participant has been randomised

Secondary outcome measures
Hypothesis 1 and 2: Classification as risky drinker according to Swedish guidelines based on the two primary alcohol-related outcome measures assessed at baseline and at 2 and 4 months

Overall study start date
10/10/2017

Completion date

31/12/2021

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Ownership of a mobile phone
3. Classified as a risky drinker according to Swedish guidelines. Note there is no upper limit to alcohol consumption as an exclusion criterion, meaning the study population is anticipated to comprise both harmful and hazardous drinkers

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2126

Total final enrolment
2129

Key exclusion criteria
1. Less than 18 years old
2. Does not own a mobile phone
3. Non-risky drinkers (according to Swedish guidelines)

Date of first enrolment
01/03/2019

Date of final enrolment
01/12/2020

Locations

Countries of recruitment
Sweden

Study participating centre

Linköping University
Sweden
58183

Sponsor information

Organisation
Linköping University

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Sponsor type
University/education

Website
https://www.liu.se

ROR
https://ror.org/05ynxx418

Funder(s)

Funder type
University/education

Funder Name
Linköpings Universitet

Alternative Name(s)
Linköping University, Linköping University, LiU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location

Sweden

Results and Publications

Publication and dissemination plan
A study protocol will be published prior to the first participant being recruited. This protocol will also include a summary of the statistical analysis plan.

Three results publications are planned:
1. Analysis of comparison of Intervention and Control groups with respect to alcohol consumption outcomes - planned for 01/03/2020
2. Participants recall of study parameters and engagement in further information (Control) - planned for 01/03/2020
3. Usability evaluation of intervention - planned for 01/06/2020

Intention to publish date
01/07/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to GDPR. There is a risk that combining data sources would identify participants through quasi-identifiers. The data will be stored at Linköping University.

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	18/04/2019	23/04/2019	Yes	No
Results article		17/05/2022	18/05/2022	Yes	No
Other publications	a study within a digital alcohol intervention trial	02/01/2024	04/01/2024	Yes	No
Results article		28/10/2023	10/01/2024	Yes	No
Other publications	Satisfaction feedback from the intervention group	11/01/2024	13/02/2025	Yes	No