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Comparing immediate and delayed initiation of online support for excessive alcohol consumption

Submission date
26/01/2021

Recruitment status
No longer recruiting

Registration date
01/02/2021

Overall study status
Completed

Last Edited
16/06/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to investigate the effects of immediate versus delayed initiation of online support for excessive alcohol consumption. The treatment will be access to online materials that are believed to help people reduce their drinking.

Who can participate?
Anyone aged 18 or older who has consumed either more than 6 drinks of alcohol on at least one occasion the past month, or who has consumed at least 10 drinks the past week can participate.

What does the study involve?
Participants will be randomly allocated to two groups. Half of the participants will receive access to online materials immediately. The other half of the participants will have to wait for 1 month to receive access to online materials. The study involves answering a few online questions and reading some online material.

What are the possible benefits and risks of participating?
The benefits including getting access to material which are believed to help people reduce their drinking. A possible risk is that receiving materials believed to help individuals, and finding that it does not help, could be de-motivating.

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

When is the study starting and how long is it expected to run for?
From March 2021 to June 2023

Who is funding the study?
This trial is investigator-initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effects of a waiting list control design on alcohol consumption among online help-seekers

Study objectives
The objective of this study is to estimate the effects immediate versus delayed initiation of online support for excessive alcohol consumption. The primary effects being estimated are the total effect and moderation by readiness to change.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/01/2021, the Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: Dnr 2020-06267

Study design
2-arm double-blind randomized wait-list controlled trial

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 the contact details to request a patient information sheet

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

Interventions
This trial will use a randomised (1:1) wait list controlled design. Block randomisation will be used with random block sizes of 2 and 4.

Individuals in both groups will receive the same personalised feedback and advice based on a baseline questionnaire. The material has been developed from previous research and is based around social cognitive theories of health behaviour. This includes:
1. Feedback on current consumption in relation to recommendations
2. Content to increase motivation and self-efficacy
3. Advice on what to do to reduce drinking and avoid environmental triggers

The treatment takes between 5 and 20 min and the follow-up period will be one month.

Intervention Type
Behavioural

Primary outcome measure
1. Frequency of heavy episodic drinking in the past month assessed by asking for the number of times in the past month the participant has consumed 6 or more drinks on one occasion at baseline and 1 month
2. Overall consumption the past week assessed by asking participants to report their consumption day-by-day at baseline and 1 month

Secondary outcome measures

1. Readiness to change measured using the readiness to change questionnaire (treatment version) at baseline and 1 month

Overall study start date
01/12/2020

Completion date
20/06/2023

Eligibility

Key inclusion criteria
1. Report having consumed ≥6 standard drinks on ≥1 occasion in the past month, or having consumed ≥10 standard drinks in the past week

Participant type(s)
All

Age group
Adult

Sex
Both

Target number of participants
A Bayesian group sequential design will be used, thus no fixed target exists. We expect no more than 1500 participants, but there are target posterior probabilities that will dictate this.

Key exclusion criteria
1. Aged ≤18 years

Date of first enrolment
29/10/2021

Date of final enrolment
01/03/2023

Locations

Countries of recruitment
Sweden

Study participating centre
Linköping University
Linköping
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Sponsor information

Organisation
Linköping University

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Sponsor type
University/education

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ROR
https://ror.org/05ynxx418

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in open access peer-reviewed journal. A research protocol with a statistical analysis plan will be submitted prior to trial commencement.

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan
Deidentified individual participant-level data will be made available upon reasonable request following publication. The data may only be used for analyses that are congruent with the

informed consent given by participants and the ethical approval of the trial. A registered study protocol must be available before data is shared.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/08/2021	31/08/2021	Yes	No