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A brief digital intervention targeting prevention of alcohol and other substance use among adolescents and young adults

Submission date
11/09/2019

Recruitment status
No longer recruiting

Registration date
24/09/2019

Overall study status
Completed

Last Edited
22/11/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The teenage years and young adulthood is a period in life when people may be especially vulnerable to harmful drug and alcohol use. Young people's brains are undergoing important development processes at this time, and substance use can negatively affect mental health and social development in the short and long term. From a public health point of view, it is important to prevent or delay substance use to reduce harm to individuals and society. There is a need for cost-effective and easily distributed interventions aimed at reducing substance use in young people. This study aims to test how well an online intervention reduces drug and alcohol use in teenagers and young adults aged 15-25 years.

Who can participate?
Teenagers and young adults aged 15-25 years who have access to the internet.

What does the study involve?
The participants will be randomly allocated to one of two groups. One group will receive the the intervention aimed at reducing substance use and some general health information. The other group will receive the health information only. Before the intervention and at 3 and 6 months after the intervention, all participants will be asked about their drug and alcohol use, their experience of peer pressure, their wellbeing and their sexual behaviour.

What are the possible benefits and risks of participating?
All participants will be provided with health information that might increase their understanding of health-related issues. Those who receive the intervention aimed at reducing substance use might benefit from reduced substance use and risky behaviours. Participants will be asked to reflect on their use of alcohol and other substances and answer questions on their mental health and family relationships. This might cause some discomfort or upset. Participants are informed that their participation is voluntary and they can interrupt or stop their participation at any time, without explanation. They will be given details of websites and phone numbers to contact for support if they have any concerns about their substance use or other problems. Any issues raised by the participants during the study will be documented and managed. The research team

includes experienced healthcare professionals, such as a psychiatrist and a nurse, who can refer participants to healthcare clinics if needed.

Where is the study run from?
STAD, Centre for Psychiatry Research, Karolinska Institutet/Stockholm County Council (Sweden)

When is the study starting and how long is it expected to run for?
May 2019 to October 2023

Who is funding the study?
1. National Public Health Agency of Sweden
2. Alcohol Research Council of the Swedish Alcohol Retailing Monopoly
3. Swedish Research Council

Who is the main contact?
Dr Pia Kvillemo, pia.kvillemo@ki.se

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
PK

Study information

Scientific Title
A brief digital intervention targeting prevention of alcohol and other substance use among adolescents and young adults: a randomised controlled trial

Study objectives
The intervention will have positive effects with regard to alcohol and other substance consumption among young people with risk use, and potential and benefit may include decreased or ceased risk behaviours

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/07/2019, Swedish Ethical Review Authority (Box 2110, 750 02 Uppsala, Sweden; +46 010-475 08 00; registrator@etikprovning.se), ref: 2019-03249

Study design
Intervention study with double-blind two-arm randomised controlled trial (RCT) design

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 substance use

Interventions
Randomisation process
The study is double-blind, thus neither the participant or the researchers know which participant is allocated to the intervention or to the active control condition. After baseline assessment, the participants will be automatically randomised to one of the two study groups by a computer program using an unrestricted randomisation protocol. Participants will then be informed about the name of their program and given access immediately.

Intervention arm
The intervention is interactive, digitally delivered in a fully automated form, and requires approximately 20 minutes to complete. Tailored feedback is given to the participants based on their responses to previous assessment and suggestions on how to respond to this feedback are

provided. This interactivity imitates a face-to face 'dialogue' with techniques from motivational interviewing (MI) such as an empathic approach, rolling with resistance, aiming at creating a dissonance between actual and desired behaviour, raising self-efficacy, and at the same time avoiding argumentation. The intervention consists of three main components and additional health-related information.

Control arm
The control group will receive the same general health-related information as those in the intervention group, i.e., the additional information provided to the intervention group.

Follow-up
Baseline assessment at study entry and two follow-up assessments at 3 and 6 months will be carried out for both groups (intervention and active control). The primary outcome is reduction in alcohol use. Secondary outcomes concern other substance use, mental health, sexual risk behaviours, and perceived peer pressure. Moreover, the study involves analyses of potential moderators including perfectionism, openness to parents, help-seeking, and background variables.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 10/01/2020:
Reduction in alcohol use, assessed by AUDIT-C and Daily Drinking Questionnaire (DDQ). Self-reported at baseline and 3-month follow-up (primary endpoint)

Previous primary outcome measure:
Reduction in alcohol use, assessed by AUDIT-C and Daily Drinking Questionnaire (DDQ). Self-reported at baseline, 3-month follow-up (primary endpoint) and 6-month follow-up

Secondary outcome measures
Self reported at baseline, 3-month follow-up and 6-month follow-up:
1. Drug use measured by Drug Use Disorder Identification Test (DUDIT)
2. Wellbeing measured by the WHO-5 Well-Being Index
3. Peer pressure measured by the Peer pressure inventory
4. Multiple choice questions regarding sexual risk behaviour.
5. Binge drinking measured by AUDIT-C (added 10/01/2020)
6. Frequency of alcohol consumption measured by AUDIT-C (added 10/01/2020)
7. Amount of alcohol consumed a typical day when alcohol is consumed measured by AUDIT-C (added 10/01/2020)

Overall study start date
01/05/2019

Completion date
15/12/2023

Eligibility

Key inclusion criteria

1. 15-25 years old
2. Positive CRAFFT screen (=2 or more)
3. Access to Internet
4. Understand Swedish language

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Both

Target number of participants
800

Key exclusion criteria
1. Not meeting inclusion criteria
2. Declined to participate after screening

Date of first enrolment
15/01/2020

Date of final enrolment
15/10/2020

Locations

Countries of recruitment
Sweden

Study participating centre
STAD, Centre for Psychiatry Research, Karolinska Institutet/Stockholm County Council
Norra Stationsgatan 69
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Sponsor information

Organisation
Karolinska Institutet

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Sponsor type
University/education

Website
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ROR
https://ror.org/04hmgwg30

Funder(s)

Funder type
Government

Funder Name
National Public Health Agency of Sweden

Funder Name
Alcohol Research Council of the Swedish Alcohol Retailing Monopoly

Funder Name
Svenska Forskningsrådet Formas

Alternative Name(s)
Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning, Swedish Research Council Formas, Formas

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Publication and dissemination plan
Study protocol to be published in a scientific journal (eg BMJ Open). Pre-post, and long-term follow-up results to be published in a scientific journal (eg BMJ Open).

Intention to publish date
31/10/2024

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date