

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 24/09/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/11/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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

Stockholm

Sweden

113 64

Sponsor information

Organisation

Karolinska Institutet

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes