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Testing the effectiveness of a web-based intervention to reduce alcohol consumption in Estonia.

Submission date
12/04/2019

Recruitment status
No longer recruiting

Registration date
04/06/2019

Overall study status
Completed

Last Edited
09/09/2021

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Misuse of alcohol is a worldwide problem that has a lot of negative consequences to public health. In 2017 alcohol consumption level reached over 10 litres of absolute alcohol per adult in Estonia. In resents years' different activities directed towards the increase of people's skills and knowledge; empower of healthcare specialist; as well as legislative initiatives (taxation, limitations on alcohol beverages advertisements) were introduced in Estonia. In this overall prevention package, a cost-effective internet based self-help programme to prevent people from developing full alcohol-dependence was missing. Therefore, the programme Take Care of You (TCOY), that was developed and positively tested in Switzerland was adapted and translated into Estonian.
The aim of this study is find out whether the use of the web-based self-help programme TCOY for harmful and hazardous alcohol users can help to reduce alcohol intake in Estonians.

Who can participate?
Adults who are hazardous alcohol users but not clinically treated.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in the first group (intervention group) are started on an 8-weeks self-help programme focusing on alcohol use via the internet. This programme provides education materials as well as teaching self-control practices and techniques to reduce cravings. The participants are asked to keep a diary throughout the 8- weeks intervention, in order to study their thoughts on the programme and see how well the treatment is working. Those in the second group (control group) are put on a waiting list. After 6 months on the waiting list, those in the control group are given the opportunity to start the online self-help programme. For both groups, at the start of the study, at two months and at six months, alcohol consumption is measured, as well as mental health issues.
What are the possible benefits and risks of participating?
Benefits of participating include a better understanding of addictive behaviour and being given tools to help handle cravings and reducing the risk of alcohol dependency. Potential risks of

participating are insignificant, however withdrawal symptoms, such as cravings, may be experienced.

Where is the study run from?
1.Estonian National Institute for Health Development (Estonia)
2. Swiss Research Institute for Public Health and Addiction (Switzerland)

When is the study starting and how long is it expected to run for?
June 2018 to December 2019

Who is funding the study?
European Social Fund and Estonian National Institute for Health Development
Who is the main contact?
Mrs Esta Kaal

Contact information

Type(s)
Scientific

Contact name
Mrs Esta Kaal

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Additional identifiers

Study information

Scientific Title
Web-based treatment trial among hazardous alcohol users: a randomised controlled trial.

Acronym
N/A

Study objectives
Tailored self-help for the reduction of alcohol use is more effective than the waiting list control condition in reducing alcohol use between the baseline and the 2 and 6 months' follow-ups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/02/2019, Tallinn Medical Research Ethics Committee's (Hiiu 42, Tallinn 11619; eetikakomitee@tai.ee; +372 659 3924; +372 659 3901), ref: 2637.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Harmful or hazardous alcohol use.

Interventions
After ensuring that potential participants are eligible for the study (i.e., after a baseline assessment), they will be randomized by a computer program to 1 of 2 parallel groups:

1. Experimental intervention: web-based self-help program focusing on alcohol; and
2. Control condition: waiting list.

The web-based self-help intervention (study arm 1) consist of a diary (assesses daily alcohol consumption) and 10 modules based on the principles of motivational interviewing, self-control practices, and methods of cognitive behavioural therapy. Participants can study all modules at their own pace and in their own order, though a specific order will be advised. This web-based self-help intervention consist of an 8-week program starting individually at the point of the user's online registration. Follow-ups will be assessed 2 and 6 months after the individual's self-chosen starting point. The control condition is a waiting-list. The follow-ups are timed as in the experimental intervention (after 2 and 6 months). After 6 months the study phase of the control condition is finished and people will be given the opportunity to start the self-help programme out of the experimental condition.

Intervention Type
Behavioural

Primary outcome(s)
Alcohol consumption, drinking behaviors, and alcohol-related problems are measured using the Alcohol Use Disorders Identification Test (AUDIT) score at 6 months' follow-up.

Key secondary outcome(s)
1. The number of standard drinks and alcohol-free days is measured using a self-report on typical week during the past 6-months.
2. Treatment retention is measured using the alcohol consumption diary every week over the 8-weeks of intervention.
3. The following is assessed at baseline, 2 months and 6 months:
3.1. Illicit drugs consumption is measured using the NIDA questionnaire.
3.2. Mental health symptoms is measured using the Mental Health Inventory questionnaire (MHI-5).

4. Motivation to drink and motivation to change are measured using the Drinking Motives Questionnaire (DMQ-R-5) and Motivation for Change Questionnaire (3 items) at baseline, 2 months and 6 months.
5. Satisfaction with the trial is measured using the "Customer Satisfaction Questionnaire" for internet interventions (iCSQ-8) in the intervention group at the end of the intervention.
6. Usage of other resources is measured in the control group at 2 months and 6 months.

Completion date
30/11/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. AUDIT score ≥ 8
3. Weekly Internet access
4. Able to read and understand Estonian language

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
589

Key exclusion criteria
1. Participation in other psycho-social or pharmacological treatments for the reduction /cessation of alcohol, opioids, stimulants or cannabis
2. In the last 12 months use of opioids or stimulants or cannabis use of more than once a week in the previous 30 days
3. Previous treatment for cardiovascular problems
4. Pregnancy or breast feeding in female participants
5. Suicidal thoughts or plans in the last 24 months

Date of first enrolment
13/03/2019

Date of final enrolment
15/04/2019

Locations

Countries of recruitment
Estonia

Switzerland

Study participating centre
Estonian National Institute for Health Development
Hiiu 42
Tallinn
Estonia
11619

Study participating centre
Swiss Research Institute for Public Health and Addiction (ISGF)
Konradstrasse 32
Zurich
Switzerland
8005

Sponsor information

Organisation
Estonian National Institute for Health Development

Funder(s)

Funder type
Government

Funder Name
European Social Fund

Alternative Name(s)
European Social Fund, Европейският социален фонд, Европейският социален фонд плюс, Fondo Social Europeo, Fondo Social Europeo Plus, Ευρωπαϊκό Κοινωνικό Ταμείο, Ευρωπαϊκό Κοινωνικό Ταμείο+, Ciste Sóisialta na hEorpa Plus, Ciste Sóisialta na hEorpa, ESF, ESF+, ΕΚΦ, ΕΚΦ+, FSE, FSE+, EKT, EKT+, CSE, CSE+

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Estonian National Institute for Health Development

Results and Publications

Individual participant data (IPD) sharing plan
The data sets generated during the current study will be available upon request from Mrs. Esta Kaal, esta.kaal@tai.ee via internet in the form of anonymised raw data set in CSV-format from 1.05.2021 to 1.05.2036. The informed consent was asked in the online form.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/06/2021	09/09/2021	Yes	No
Protocol article	protocol	27/05/2020	01/03/2021	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes