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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

Study website
https://selge.alkoinfo.ee/?q=homepageguest

Contact information

Type(s)
Scientific

Contact name
Mrs Esta Kaal

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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
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.

Study design
Randomised 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 contact details to request a participant information sheet.

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

Secondary outcome measures
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.

Overall study start date
21/06/2018

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

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600 (2 groups of 300)

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
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Sponsor information

Organisation
Estonian National Institute for Health Development

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Sponsor type
Research organisation

Website
https://www.tai.ee/en/

Funder(s)

Funder type
Government

Funder Name
European Social Fund

Alternative Name(s)
Европейският социален фонд, Evropský sociální fond, Den Europæiske Socialfond, Europäischer Sozialfonds, Euroopa Sotsiaalfond, Ευρωπαϊκό Κοινωνικό Ταμείο, Fondo Social Europeo, Fonds social européen, Europski socijalni fond, Fondo sociale europeO, Eiropas Sociālais fonds, Europos socialinis fondas, Európai Szociális Alap, Fond Soċjali Ewropew, Europees Sociaal FondS, Europejski Fundusz Społeczny, Fundo Social Europeu, Fondul Social European, Európsky sociálny fond, Evropski socialni sklad, Euroopan sosiaalirahasto, Europeiska socialfonden, European Social Fund, Fondo Social Europeo Plus, Европейски социален фонд плюс, Evropský sociální fond plus, Europæiske Socialfond Plus, Europäische Sozialfonds+, Euroopa Sotsiaalfond+, Ευρωπαϊκό Κοινωνικό Ταμείο+, Fonds social européen+, Europski socijalni fond plus, Fondo sociale europeo Plus, Eiropas Sociālais fonds Plus, Europos socialinis fondas +, Európai Szociális Alap Plusz, Europees Sociaal Fonds Plus, Europejski Fundusz

Społeczny Plus, Fundo Social Europeu Mais, Fondul social european Plus, Európsky sociálny fond +, Evropski socialni sklad +, Euroopan sosiaalirahasto plus, Europeiska socialfonden+, ESF, ЕСФ, EKT, FSE, ESZA, EFS, ESS, ESR, ESF+, ESZA+, EFS+, FSE+, ESS+, ESR+

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Estonian National Institute for Health Development

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal and study report for local use.

Intention to publish date
31/12/2020

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?
Protocol article	protocol	27/05/2020	01/03/2021	Yes	No
Results article		29/06/2021	09/09/2021	Yes	No