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Testing the effectiveness of two web-based interventions aiming to reduce alcohol consumption

Submission date
07/09/2015

Recruitment status
No longer recruiting

Registration date
08/09/2015

Overall study status
Completed

Last Edited
09/09/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Misuse of alcohol and alcohol dependence are a growing problem worldwide. Many people show signs of drinking too much alcohol, or drinking alcohol at inappropriate times (hazardous alcohol use), and are at risk of developing alcohol dependence, often known as “alcoholism”. There is a great deal of evidence suggesting that drinking too much alcohol can lead to mental illnesses such as depression. Providing an inexpensive self-help programme using the internet to prevent people from developing full alcohol-dependence could be very beneficial from a public health point of view. Additionally, this programme could be used to help treat the feelings of depression that often accompany alcohol misuse. The aim of this study is find out whether the use of a web-based self-help programme for hazardous alcohol users with mild to moderate depression can help to reduce alcohol intake and alleviate symptoms of depression.

Who can participate?
Adults who are hazardous alcohol users with mild to moderate feelings of depression.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in the first group (intervention group) are started on a 6 week 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 6 week 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 three months and at six months, alcohol consumption is measured, as well as mental health issues (such as depression). The cost-effectiveness of the programme is also measured at these time points.

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, reducing the risk of alcohol dependency. Additionally, for participants in the alcohol and depression group, their feelings of depression may be reduced. Potential risks of participating are insignificant, however withdrawal symptoms, such as cravings, may be experienced.

Where is the study run from?
1. Swiss Research Institute for Public Health and Addiction (Switzerland)
2. Leuphana University (Germany)
3. Arkin Mental Health Care (Netherlands)
4. Amsterdam Institute for Addiction Research (Netherlands)
5. VU University of Amsterdam (Netherlands)

When is the study starting and how long is it expected to run for?
November 2015 to January 2018

Who is funding the study?
Swiss Foundation for Alcohol Research (Switzerland)

Who is the main contact?
Dr Michael Schaub

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Web-based Dual Disorder Treatment Trial among Problematic Alcohol Users with Moderate Depression Symptoms

Study objectives
The objective will be to test the effectiveness of a web-based intervention aiming to reduce alcohol consumption and depression symptoms combined, a web-based self-help intervention focusing on problematic alcohol use only, and a waiting list control condition in hazardous and harmful alcohol users with co-morbid mild to moderate depression symptoms.

We will test the following detailed study hypotheses with respect to the reduction of the quantity of weekly standard drinks and depression symptoms between the baseline and the 3 and 6 months follow-up:

1. Tailored self-help for the reduction of alcohol use and depression symptoms (study arm 1) is more effective than the waiting list control condition (study arm 3) in reducing alcohol use and depression symptoms.
2. Tailored self-help for the reduction of alcohol use (study arm 2) is more effective than the waiting list control condition (study arm 3) in reducing alcohol use but not depression symptoms.
3. Tailored self-help for the reduction of alcohol use and depression symptoms (study arm 1) is more effective than self-help for the reduction of alcohol use only (study arm 2) in the reduction of depression symptoms but not in the reduction of alcohol use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Canton of Zurich, 07/04/2015, ref: KEK-ZH-Nr: 2015-0082

Study design
Randomized controlled trial with web-based psychological intervention

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
1. Harmful or hazardous alcohol users
2. Mild to moderate co-occurring depression symptoms

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 3 parallel groups:

1. Experimental Intervention 1: Web-based self-help program focusing on alcohol and depression;
2. Experimental Intervention 2: Web-based self-help program focusing on alcohol; and
3. Control Condition: waiting list.

Both web-based self-help interventions (study arms 1 and 2) consist of a diary and several (currently 8) 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. For the alcohol-only group, the diary will assess the daily alcohol consumption. For the alcohol and depression group, the diary will assess the daily alcohol consumption, mood and positive activities. Both web-based self-help interventions consist of a 6-week program starting individually at the point of the user's online registration. Follow-ups will be assessed 3 and 6 month after the individual's self-chosen starting point. The control condition is a waiting-list. The follow-ups are timed as in the experimental interventions (after 3 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 of experimental condition 1.

Intervention Type
Behavioural

Primary outcome measure
The number of weekly standard drinks will be assessed with timeline follow-back (TLFB) at baseline, 3 months and 6 months.

Secondary outcome measures
1. Depressive symptoms assessed with the "Center of Epidemiologic Studies of Depression" (CES-D-20) at baseline, 3 months and 6 months
2. Use of tobacco and illicit drugs assessed with the "Fragebogen Substanzanamnese" questionnaire (FDA) at baseline, 3 months and 6 months
3. Changes in mental health symptoms assessed with the Mental Health Inventory questionnaire (MHI-5) at baseline, 3 months and 6 months
4. Treatment retention measured by using the diary every week over the 6-weeks of intervention
5. Cost-effectiveness-analyses assessed with the EuroQol Quality of Life questionnaire (EQ-5D-3L) at baseline, 3 months and 6 months
6. Cost-utility-analysis and client intervention satisfaction assessed with the Questionnaire on healthcare utilization and productivity losses (TiC-P) at baseline, 3 months and 6 months
7. The "Customer Satisfaction Questionnaire" (CSQ-8) is used as secondary outcome only for participants who have received web-based self-help intervention for 6 weeks (i.e., not used for the control group) measured every week over the 6-weeks of intervention
8. Drinking behaviour is determined using the total score of the short version of the Alcohol Use Disorders Identification Test (AUDIT-C) at baseline, 3 months and 6 months

Overall study start date
01/11/2015

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. Age 18 years or over
2. AUDIT score ≥ 8 and ≤ 20 (AUDIT = Alcohol Use Disorder Inventory Test)
3. CES-D-20 score greater than 16 (Center of Epidemiological Studies of Depression)
4. Weekly Internet Access

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
756 (3 groups à 252)

Total final enrolment
689

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

Date of first enrolment
01/11/2015

Date of final enrolment
31/07/2017

Locations

Countries of recruitment
Germany

Netherlands

Switzerland

Study participating centre
Swiss Research Institute for Public Health and Addiction
Konradstrasse 32
Zurich
Switzerland
8031

Study participating centre
Leuphana University
Scharnhorststraße 1
Lüneburg
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21335

Study participating centre
Arkin Mental Health Care
Klaprozenweg 111
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Netherlands
1033

Study participating centre
Amsterdam Institute for Addiction Research
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Netherlands
1105

Study participating centre
VU University of Amsterdam
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1081

Sponsor information

Organisation
Swiss Foundation for Alcohol Research

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Sponsor type
Government

Website
http://www.alcoholresearch.ch/en/1.html

Funder(s)

Funder type
Research organisation

Funder Name
Swiss Foundation for Alcohol Research

Results and Publications

Publication and dissemination plan
Not provided at time of registration.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/05/2016		Yes	No
Results article		01/08/2021	09/09/2021	Yes	No