First web-based Dual Disorder Treatment Trial among Problematic Alcohol Users with Moderate Depression Symptoms

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON42578

Source
ToetsingOnline

Brief title
ALCDEP

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
alcohol misuse, problem drinking

Research involving
Human

Sponsors and support

Primary sponsor: Arkin (Amsterdam)
Source(s) of monetary or material Support: Interne financiering Arkin + financiering door Swiss Foundation for Alcohol Research

Intervention

Keyword: alcohol, depression, internet-based, self-help

Outcome measures

Primary outcome

The primary outcome will be the amount of standard drinks in the week prior to data collection.

Secondary outcome

The secondary outcomes will be depressive symptoms, the use of tobacco and illicit drugs, changes in mental health symptoms and client intervention satisfaction.

Study description

Background summary

Web-based self-help programs that reduce problematic substance use are able to reach *hidden* consumer groups in the general population who often fear stigmatization. These programs are characterized by their low treatment threshold, non-restrictive setting for intervention and remarkably positive cost-benefit relation, which is of interest for both low-income and high-income industrialized countries suffering from exorbitant health costs.

There is substantial co-occurrence of mental disorders and substance use disorders. Prevalence of dual disorders, the condition of suffering from a mental illness and a co-morbid substance abuse problem, is probably highest in the general population for individuals with depression disorders and problematic alcohol use. Co-morbidity of alcohol misuse and abuse is two to three times higher for those who suffer from depression disorders compared to the general population.

Internet-based self-help programs to reduce subclinical alcohol use disorders or ameliorate moderate to mild depression symptoms have been reported to be effective in meta-analyses. A cost-effective intervention that is able to reach at-risk individuals in early stages of potentially more pronounced alcohol use and depression disorders is of great importance from a public health point of

view.

Therefore we aim to develop the first web-based dual disorder self-help intervention for harmful or hazardous alcohol users with mild to moderate co-occurring depression symptoms and to test this intervention*s effectiveness in a randomized controlled trial.

Study objective

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.

Study design

This study will be a three-arm randomized controlled trial that will test the effectiveness of two web-based 6 weeks self-help interventions for reducing or enabling the abstention from alcohol use in problematic users with depressive symptoms. One intervention will focus on alcohol only while the other will focus on alcohol and depression treatment combined. Total sample size is aimed at 252 participants from the Netherlands (756 participants in total, from the three participatingcountries). Follow-Ups will be assessed 3 and 6 month after the individual*s self chosen starting point.

The study will comprise 3 arms:
1) Experimental Intervention 1: Web-based self-help program focused on alcohol and depression
2) Experimental Intervention 2: Web-based self-help program focused on alcohol
3) Control Condition: Waiting list

Once participants have completed their baseline assessment, they will be randomized by a computer program in a 1:1:1 ratio to 1 of 3 parallel groups.

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.

Data will be analysed according to the intention-to-treat principle (ITT). For the ITT analyses, we will apply the multiple imputations procedure (MICE) of STATA, which imputes missing data using all available baseline variables (socio-demographic, health- and alcohol-related variables).

Baseline measurements will be compared using t- and Chi-squared tests. Differences between primary and secondary outcome variables between baseline and the follow-up will be tested using generalized estimating equation (GEE) models.

All data inputs from participants is entered and accessed via 128bit encrypted and password protected SSL-Connections over a website.

Intervention

The web-based self-help intervention will 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.

In intervention 1 the diary will asses alcohol consumption, mood and positive activities. The modules will focus on alcohol reduction and depression treatment combined.

In intervention 2 the diary will assess alcohol consumption only. The modules will focus on alcohol reduction only * though the length will approximately be the same as in intervention 1.

The control condition is a waitinglist. After 6 months their study phase is finished and they will be given the opportunity to start the self-help programme of experimental condition 1.

Study burden and risks

Potential risks are expected to be minimal as no drugs or medical devices are used. What we expect are withdrawal symptoms, like craving or depressive resentments. These issues will be adressed in the psychoeducative modules which are part of the 6 week selfhelp-intervention. At all time an *instant help*-webpage is available with instructions what to do if the situation gets unbearable. These instructions contain psychoeducative selfhelp instructions as

well as phone numbers to health care takers from the public sector.

The benefits of the intervention reach from a better understanding of one*s addictive behaviour, through having some psychological tools to handle craving and prevent relapses up to being released from alcohol dependency and/or amelioration of depressive symptoms.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age * 18 years
AUDIT score * 8 and * 20
CES-D-20 score * 16

Weekly Internet Access (or more)

Exclusion criteria

Participation in other psycho-social or pharmacological treatments for the reduction/cessation of alcohol use or the reduction of depression symptoms
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
Ever been in treatment for cardiovascular problems
Suicidal ideation or plans in the last 12 months
for female participants: pregnant and/or breast feeding

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	252
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-11-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL53374.029.15