Efficacy of an internet-based alcohol reduction self-help for young adults with co-occurring depression and alcohol misuse

Published: 07-12-2018
Last updated: 19-03-2025

The aim of the study is to reduce depression symptoms and alcohol intake simultaneously in a population of young adults with a depressive disorder and problematic alcohol use. For this study online CBT/MI based alcohol reduction self-help add-on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49219

Source
ToetsingOnline

Brief title
Blended Alcohol Depression E-health

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
depression, depressive disorder

Health condition

problematisch alcoholgebruik

Research involving
Human

Sponsors and support

Primary sponsor: Arkin (Amsterdam)
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Alcohol misuse, Depression, Ehealth, Young adults

Outcome measures

Primary outcome

The primary research outcome is a treatment response variable: alcohol and depression related measures that are combined into a composite score which indicates if the intervention has been succesfull or not.

The treatment response is successful when all three criteria below are met:

1) men drink less than 21 glasses and women less than 14 glasses of alcohol per week in the week prior to measurement;

2) 0 days of 4 or more glasses of alcohol for women or 5 or more glasses of alcohol for men in the last seven days;

3) a CES-D (depression) score of <16 or a reduction of 40% in comparison with the CES-D score measured at baseline.

Secondary outcome

There are three secondairy outcome measures in this study:

1) Alcohol use

2) Depression symptoms

3) Quality of live

Furthermore, an economic evaluation will be performed alongside the RCT, to

test for cost-effectiveness of the intervention compared to care as usual.

Study description

Background summary

Problematic alcohol use often co-occurs with major depressive disorder (MDD), both in treatment populations (Schuckit, 2006) as well as in the general population (Boschloo et al 2011). MDD treatment populations have up to 40% life-time probability of developing problematic alcohol use (Cranford et al 2011). The co-occurrence of problematic alcohol use and MDD results in even greater disease burden and higher societal costs than the separate disorders (Gadermann et al 2012; Riper et al 2014).

Various studies have shown that often MDD tends to occur prior to alcohol use disorder (Briere et al 2014; Boschloo et al 2011; Kuo et al 2006). Briere et al (2014) found MDD in early adulthood to predict alcohol problems in adulthood. Furthermore, comorbidity more than doubled the risk of alcohol problem severity. Also consistent with previous studies it was found that comorbidity is associated with poorer functioning and life satisfaction than pure MDD /problematic alcohol use (Briere et al 2014). Whether and how treatment should be modified in cases of successive comorbidity is an understudied area that requires further attention. Intervening in MDD early adulthood may help to prevent subsequent alcohol use disorder (Briere et al 2014).

A recent review on alcohol use and depression among adolescents and young adults also concludes that there is evidence supporting the association between MDD and problem drinking, such that mood problems contribute to the onset of alcohol problems, and that this association is bi-directional. To date, findings suggest the critical need to reduce any alcohol use at a young age and to address both depression and problematic alcohol use to prevent the occurrence of comorbid disorders (Pedrelli et al 2016).

Combined treatment of comorbid alcohol problems and MDD could hence be vitally important from a clinical and a public health viewpoint (Riper et al 2014), especially for adolescents and young adults. Combined treatment has never been common clinical practice as the comorbid disorder was either not recognized or was not treated, assuming that it would resolve once the primary disorder was treated effectively (Pettinati et al 2013).

Today, a growing number of combined treatments for comorbid problematic alcohol use and MDD are available; these include psychotherapeutic treatments either as

an adjunct to treatment as usual (TAU) or as an alternative to it. Based on a recent systematic review, there is some evidence that these combined interventions can be effective for adults (Riper et al 2014). This review concludes that combined cognitive-behavioural therapy (CBT) and motivational interviewing (MI) for (sub-) clinical depression and problematic drinking has a clinically significant effect in treatment outcomes (g=.17 for alcohol; g=.27 for depression) compared with treatment as usual. In this review, digital interventions showed a higher effect size for depression than face-to-face interventions (g=.73 vs. g=.23, P=.03).

For problem drinking, there is no evidence that digital interventions have an effect size that differs from face-to-face interventions. For patients with both MDD and problematic alcohol use patterns, combined treatment can reduce symptoms, increase life satisfaction and quality of life, and may increase patients* treatment satisfaction to a greater extent than single disorder-focussed treatment (see Riper et al 2014). Thus, combined treatments may also be more cost-effective than single disorder-focussed treatment (Schaub et al 2016).

However, evidence on the effectiveness, and the availability of combined depression and alcohol interventions tailored at young people is currently insufficient.

Study objective

The aim of the study is to reduce depression symptoms and alcohol intake simultaneously in a population of young adults with a depressive disorder and problematic alcohol use. For this study online CBT/MI based alcohol reduction self-help add-on modules tailored for young people in depression therapy will be developed. In a multicentre randomized clinical trial effectiveness of treatment as usual + internet-based alcohol reduction self-help add-on modules on alcohol and depression outcomes against treatment as usual (TAU) will be evaluated. In addition, an economic evaluation will be performed alongside the RCT.

Study design

Multicenter, single blind, 2-arm randomized controlled trial.

Intervention

The online selfhelp consists of six online alcohol reduction 'add-on' modules and will be based on existing (guided) selfhelp for alcohol use reduction from Arkin/Jellinek. The alcohol modules will be based on cognitive behavior therapy and motivational interviewing en will be tailered to young adults in depression treatment (including students). Although the modules will mainly be selfhelp, a

light level of support will be available (e.g. personal feedback on assignments by a coach (no care related taks)). Each module will consist of assignments and psycho-education. Each module will take about 45 minutes to complete. De following theme's will be included:

module 1: (dis)advantages of alcohol use and (dis)advantages of changing alcohol drinking behavior and motivation for change
module 2: self-control measures
module 3: setting drinking goals
module 4: making an emergency plan when someone drank more than was allowed according to their drinking goals
module 5: handling cravings, alcohol refusal skills
module 6: aftercare module (without support) continuing registration of alcohol use and reference to support/selfhelp groups

Study burden and risks

Expectation of burden:
All participants will be asked to fill out one online baseline questionniare and three follow-up online questionnaires. Filling out the questionnaire will take about 45 minutes per questionniare.

Participants who are included in the intervention group will be asked to follow the online selfhelp alcohol reduction modules. The six online alcohol modules consist of pscyho-education and assignments according to specific alcohol related themes. It will take about 45 minutes to complete the module and its assignments.

Expecation of associated risks:
The expected risk concerning participation in this study are expected to be negligible. Possible risk for paticipants that follow the online alcohol modules could entail mild withdrawal symptoms such as craving. Furthermore, all participants are asked to fill out the follow-up questionnaires and/registration of alcohol intake. Therefore, they might could be more aware of negative feelings concerning alcohol intake or if they relapsed.
Participants that follow the online alcohol modules will receive tips about how to handle cravings and how to deal with situations in which they drink more alcohol than they should.

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

Depressive disorder as a diagnosis
Age 18-35
AUDIT score of *8 for men and *5 for women
Moderately proficient in Dutch
Willing to provide contact details including (mobile)phone
Healthcare insurance coverage
Computer/tablet at home and willingness to use this for research purposes
Informed consent regarding the study provided by the patient

Exclusion criteria

Acute psychosis
Alcohol dependence (DSM-4) or severe alcohol use disorder (DSM-5) as primary diagnosis
Dementia
Waitlisted for in-patient mental health care

Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2019
Enrollment:	156
Type:	Actual

Medical products/devices used

Generic name:	software
Registration:	No

Ethics review

Approved WMO Date:	07-12-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-09-2020
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23390
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66899.100.18
OMON	NL-OMON23390