Blended Alcohol Depression Ehealth

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23390

Source
Nationaal Trial Register

Brief title
BLADE

Health condition

Depression, alcohol misuse

Sponsors and support

Primary sponsor: Arkin Institute for Mental Health
Source(s) of monetary or material Support: ZonMw (The Netherlands Organisation for Health Research and Development)

Intervention

Outcome measures

Primary outcome

Treatment respons: the treatment response outcome measure combines alcohol and depression measures into a composite score which indicates whether treatment has been successful or not. The treatment is deemed successful if all three conditions below are met:
- Drinking less than 21 (males) / 14 (females) glasses of alcohol in the week prior to measurement. 'Glasses' is operationalized as standard drinks which contain 10 g of ethanol (the European standard);

- 0 days with 4 or more (women), or 5 or more (men) drinks reported in the last 7 days;
- Center for Epidemiological Studies-Depression (CES-D) score < 16 or a reduction of 40% relative to CES-D at baseline.

Secondary outcome

- Alcohol use (AUDIT & Timeline Followback)
- Depression symptoms (CES-D)
- Quality of life (EQ-5D-5L & MOS SF-36)

Study description

Background summary

Objective: To evaluate the (cost-) effectiveness of adding an internet-based alcohol reduction intervention to depression treatment (TAU), in reducing alcohol and depression outcomes compared to TAU alone among young adults aged 18-35 years.

Study design: A multicentre, 2-arm randomized controlled trial. Assessments take place at baseline, 3 months, 6 months (primary endpoint) and 12 months.

Study population: Patients diagnosed with a depressive disorder enrolling for or in depression treatment, age 18-35, and a total score of ≥ 8 for men and ≥ 5 for women on the Alcohol Use Disorder Identification Test (AUDIT).

Intervention: The intervention group receives TAU + guided online alcohol reduction intervention (self-help modules). The content of these modules aimed at reducing alcohol use and is based on existing internet-based self-help materials and on cognitive behaviour therapy and motivational interviewing (CBT/MI) and are tailored for young people in depression therapy. TAU consists regular CBT or other evidence-based psychotherapy combined with medication if necessary. TAU is directed at activation and identification of maladaptive cognitions. Control group receives TAU alone.

Main study parameters/endpoints: The primary outcome is treatment response, a composite score that combines alcohol and depression measures which in indicates whether treatment has been successful or not.

Study objective

We expect to find an 25% treatment response for TAU and 50% treatment response for TAU + online alcohol reduction intervention.

Study design

T0 = Baseline
T1 = 3 months follow-up
T2 = 6 months follow-up (primary endpoint RCT)
T3 = 12 months follow-up

Intervention

The intervention group receives blended TAU + a guided web-based alcohol reduction intervention. Guidance is focused on process support (no care related guidance). The content of the modules is based on existing internet-based (guided) self-help materials developed by Arkin/Jellinek and is based on cognitive behaviour therapy and motivational interviewing (CBT/MI) and tailored for young people in depression therapy. The online alcohol reduction intervention consist of 5 modules + 1 aftercare module, conceptually in line with the evidence-based brief CBT for adults and exists mainly of information (in text and video) and short assignments and registration of daily alcohol intake and mood. A prototype of the online intervention was evaluated for usability in focus groups by clients and therapists. Based on the input from these focus groups adjustments were made to the final online alcohol intervention. The online alcohol reduction intervention can be accessed on computer and other mobile devices (e.g. smartphone/tablet).

Both groups will receive TAU. The control group will receive TAU alone. The TAU has a duration of 4-6 months. TAU consists of 8 to 16 45-minutes sessions of regular Cognitive-Behavioural Therapy (CBT) or other evidence-based psychotherapy (e.g. interpersonal psychotherapy, problem solving therapy), combined with medication if necessary.

Contacts

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Eligibility criteria

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 treatment and research purposes
- Informed consent regarding the study provided by the patient

Exclusion criteria

- Acute psychosis
- Alcohol dependence 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	18-11-2019
Enrollment:	156
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
NA

Ethics review

Positive opinion
Date: 29-10-2019
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49219
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8122
CCMO	NL66899.100.18
OMON	NL-OMON49219

Study results

Summary results
NA