A randomized, controlled trial on the added value of online cognitive bias modification avoid-alcohol training (CBM AAT) on web-based cognitive behavioural treatment (TAU) for problem drinkers

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

Summary

ID

NL-OMON42123

Source
ToetsingOnline

Brief title
Web-based treatment + CBM avoid alcohol training

Condition

- Other condition

Synonym
alcohol use problems, problem drinkers

Health condition

probleemdrinkers

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: NWO Veni subsidie 451-10-029;tevens Tactus en promotiegelden van Saxion University of Applied Sciences

Intervention

Keyword: Cognitive Bias Modification, problem drinkers, psychological treatment

Outcome measures

Primary outcome

The main study parameter is the percentage of participants reporting alcohol consumption below problem drinking limits (<22 standard units/week for men and <15 for women).

Secondary outcome

Health status will be assessed with the Maudsley Addiction Profile, Health Symptom Scale (MAP-HSS). The MAP-HSS is a ten-item structured interview, which was adapted from the health scale of the Opiate Treatment Index (Marsden et al., 1998).

Quality of life will be measured with the EuroQol-5D (EQ-5D) (Lamers et al., 2005). The EuroQol-5D is a generic quality-of-life (QoL) instrument which consists of 5 domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. In addition, participants were asked to rate quality of life in the last week, in comparison with last year, by means of a visual analogue scale (VAS).

Depression, anxiety and stress will be measured with the 21-item Depression Anxiety Stress Scale (DASS-21) (Antony et al., 1998).

Approach-bias: Approach-bias is measured with an AAT (Wiers et al., 2009),), in the pre-assessment and post-assessment. The assessment AAT will begin with 12 practice pictures in which participants learn to avoid or approach the picture in response to the tilt of the picture (tilted left or right). The practice phase will be followed by the pre-assessment, consisting of 160 test pictures in which pictures of alcoholic drinks and non-alcoholic drinks come equally often in push- or pullformat (e.g. tilted left and right). To control for confounding by left-right preferences picture format will be counterbalanced, with half the participants pulling pictures tilted to the left and half pulling pictures tilted to the right. An AAT bias index is calculated as the difference between the median reaction time scores for pushing pictures of one category (alcohol or soft drinks) and the median reaction time score for pulling pictures of that category. Median scores are used to minimize the influence of outliers. Positive scores indicate approach tendencies and negative scores indicate avoidance tendencies.

Background variables that will be assessed at baseline are gender, age, education level, employment, alcohol dependence, and treatment motivation. We will also assess the number of completed sessions and TAU sessions.

Type and severity of alcohol dependence at baseline will be assessed by using

the DSM-IV, by means of the Substance Abuse Module of the Composite International Diagnostic Interview (Compton et al., 1996).

Baseline Drinking Motives will be measured with the modified Drinking Motives Questionnaire Revised (mDMQ-R, Cooper, 1994). The mDMQ-R is a 28-item self-report inventory that assessed the relative frequency of drinking for each of the four motives in Cooper*s (1994) model. Participants indicate their relative frequency of alcohol use for each of the listed reasons on a scale ranging from 1 (almost never/never) to 5 (almost always/always).

The 5-item Obsessive Compulsive Drinking Scale (OCDS) is derived from the original 14-item OCDS scale. The OCDS reflects obsessionality and compulsivity related to craving and drinking behavior (Anton et al., 1995).

Drinking Refusal Self-efficacy (Oei et al., 2005) will be assessed with 8 items covering all 3 subdimensions of self-efficacy: social pressure, emotional relief, and opportunistic. Drinking refusal self-efficacy is considered an important cognitive mechanism within the reflective system that predicts treatment outcome. We hypothesize that when baseline self-efficacy is low, the additional effect of the CBM Avoid Alcohol training will be stronger. Additionally, time-varying self-efficacy is expected to mediate the CBM effect as repeated experiences of successful coping due to stronger avoidance responses will enhance refusal self-efficacy.

Credibility of the CBM training will be assessed with the Credibility and Expectancy Questionnaire (CEQ, Devilly & Borkovec, 2000). Directly after the first session of training, participants complete this questionnaire It contains six items and differentiates between one*s thoughts and feelings regarding the CBM training.

Client Satisfaction regarding the CBM training will be assessed with the Client Satisfaction Questionnaire (CSQ; de Brey, 1983).The questionnaire contains 8 items and answers are given on a 4-point scale.

Study description

Background summary

Recent theoretical models emphasize the role of automatic processes in alcohol addiction. A new development is Cognitive Bias Modification (CBM) training; a computerised training program specifically designed to reduce automatic biases in information processing with the aim of reducing problematic drinking. The aim of the current study is to examine the effectiveness of the training as an adjunct to treatment as usual (TAU) in an outpatient web-based treatment setting in the Netherlands.

Study objective

The primary objective is to test whether adding online CBM Avoid Alcohol training (compared to a placebo training) to a web-based cognitive behavioral treatment (TAU) has an added effect on decreasing weekly alcohol consumption in problem drinkers. Secondary objectives are investigating 1) generalization to health status, quality of life, depression, anxiety and stress; 2) whether the added effect on treatment outcome is mediated by the amount of change in approach-bias; 3) who benefits most from training (testing moderation), and 4) testing adherence, acceptability, and credibility.

Study design

It is a double-blind placebo controlled intervention study with pre- and

post-assessments and two follow-up assessments (three and six months follow up).

Intervention

The Web-based TAU consists of a structured, online CBT program in which the participant and the therapist communicate asynchronously, via the Internet only. Regarding CBM Avoid Alcohol training, all participants receive pictures of alcoholic beverages and soda drinks, that are tilted to the left or right. All participants are instructed to approach one type of tilt (e.g., tilted left) by pushing a certain key (and the picture grows bigger) and avoid to other type of tilt (e.g., tilted right) by another key (and the picture shrinks). Participants in the CBM Avoid Alcohol training proved to avoid mostly alcoholic pictures and approached most soda drinks, while participants in the placebo training approached and avoided those pictures equally often. The training consists of a pre- and postassessment (with 160 pictures per assessment) and 8 training sessions (with 192 pictures per session).

Study burden and risks

With regard to risks associated with participation, it is highly unlikely that participants will suffer any negative consequences of the CBM training or placebo-training. CBM training involves a simple computerized performance task, that is non-invasive, requires little cognitive effort, and does not affect the personal integrity of participants. With regard to the burden involved, participants are required to do 2 CBM sessions weekly during 5 weeks, and participants have to fill in questionnaires that will take approximately 45 minutes in total (spread over 4 measurements).
Participation will benefit participants in both groups as the TAU Alcoholdebaas.nl has been shown an evidence based treatment for problem drinking. The expected benefit of the additional CBM training is in the first place a higher likelihood of achieving a safe alcohol consumption level.
The medical risks, like severe withdrawal symptoms are controlled in the TAU according to a protocol. Following the protocol, the TAU starts after the general practitioner has given consent to participate by completing a referral note. During treatment medical and acute risks are closely monitored by the individual social worker. If necessary the social worker contact the general practitioner. When participants, after finishing the first diagnostic part of the TAU, start to drink less or stop drinking, a multidisciplinary team decides whether the participant may start with these behavior. If there is a risk of withdrawal symptoms, the access to part 2 is denied. The participant will then be referred to the general practitioner for medical assistance or will be advised to follow another more appropriate form of treatment.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patients who will be treated in the web-based TAU, have indicated themselves that they have an alcohol problem and can be included in the study.
Since patients access the web-based TAU and CBM training at home online, it is essential that they have an internet connection. Good command of the Dutch language is also needed; Dutch as first language is therefore also an inclusion criterion.

Exclusion criteria

There are no additional exclusion criteria on top of the criteria that Tactus applies for participation in the web-based TAU. These exclusion criteria are: (1) serious psychiatric illnesses with a chance to decompensate while decreasing alcohol consumption; (2) a chance

of severe physical illnesses as a consequence of decreasing alcohol consumption. behavior.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2015
Enrollment:	304
Type:	Actual

Ethics review

Approved WMO

Date:	17-02-2015
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

ID: 24326
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL48563.018.14
OMON	NL-OMON24326