

An RCT on cognitive bias modification for alcohol use disorders in a religion-based rehabilitation program

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The present study aims to assess the effectiveness of a religion-adapted CBM intervention compared to a standard, non-religion CBM intervention, and sham intervention based on approach bias modification (ApBM).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51246

Source

ToetsingOnline

Brief title

Detoxification & Cognitive Bias Modification (DCBM)

Condition

- Other condition

Synonym

Alcohol Use Disorder; Alcohol Addiction

Health condition

Stoornis in alcoholgebruik

Research involving

Human

Sponsors and support

Primary sponsor: Stichting De Hoop (Dordrecht)

Source(s) of monetary or material Support: Stichting tot Steun VCVGZ

Intervention

Keyword: Addiction, Alcohol use disorder, Cognitive bias, Religion

Outcome measures

Primary outcome

The primary outcome will be recovery consisting of (1) the percentage of days abstinent the past month at four months follow-up using the Timeline Followback (TFLB) method and (2) meaning in life using the Multidimensional Existential Meaning Scale (MEMS).

Secondary outcome

Secondary outcomes will be training satisfaction with a 9-point Likert scale and AUD symptoms with the Leeds Dependence Questionnaire (LDQ).

Study description

Background summary

Alcohol-related cues in the environment are important triggers for relapse in patients with Alcohol Use Disorder (AUD). These cues may automatically activate motivational approach tendencies that promote alcohol seeking. Through computerized cognitive bias modification (CBM), the tendencies of patients with AUD to approach alcohol can be reduced. CBM methods are helpful but can be improved by the involvement of patients' characteristics of religiosity and meaning in life (MiL).

Study objective

The present study aims to assess the effectiveness of a religion-adapted CBM intervention compared to a standard, non-religion CBM intervention, and sham

intervention based on approach bias modification (ApBM).

Study design

Using a double-blind multi-arm parallel randomized controlled trial (RCT) procedure (ratio 1:1:1), 120 patients with AUD will be randomized into one of three conditions (religion-adapted ApBM, standard ApBM, or sham ApBM), with personalized stimuli and will be evaluated on training satisfaction after the training, abstinence, AUD symptoms and MiL four months after the intervention.

Intervention

In addition to treatment as usual (TAU) all participants receive four sessions of a 15 minutes training on the computer and responding with a joystick to self-selected pictures. The training is expected to decrease relapse due modification of alcohol stimuli and increasing approach of self-selected religious pictures (religion-adapted ApBM) or non-alcohol pictures (standard ApBM).

Study burden and risks

Participants will benefit from the ApBM intervention. To our knowledge, there are no risks associated with the usage of ApBM interventions during detoxification, but the computer tasks and questionnaire completion may be stressful.

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

- (a) Classified AUD following DSM-5 criteria
- (b) Being 18 years of age or older
- (c) Being enrolled as a patient for the detoxification program
- (d) Speak Dutch fluently
- (e) Provide informed consent (IC) before participation

Exclusion criteria

- (a) History of severe neurological disorders (like Korsakoff syndrome)
- (b) Acute psychotic symptoms
- (c) Visual or hand-motoric handicaps

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 03-09-2021
Enrollment: 120
Type: Actual

Ethics review

Approved WMO
Date: 17-05-2021
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	NL75499.018.20