

Detoxification & Cognitive Bias Modification

No registrations found.

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

Summary

ID

NL-OMON21035

Source

Nationaal Trial Register

Brief title

DCBM

Health condition

Alcohol Use Disorder

Sponsors and support

Primary sponsor: De Hoop GGZ; Stichting tot Steun VCVGZ

Source(s) of monetary or material Support: De Hoop GGZ

Intervention

Outcome measures

Primary outcome

- (1) Percentage of days abstinent at four months follow-up
- (2) Meaning in Life

Secondary outcome

- (1) AUD symptoms
- (2) Training satisfaction

Study description

Background summary

Rationale:

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).

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.

Study population: Participants will be patients (>18 years) with AUD staying at a detoxification department at De Hoop ggz without a history of severe neurological disorders, no acute psychotic symptoms, no visual or hand-motoric handicaps, and no difficulties with the Dutch language.

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).

Main study parameters/endpoints: The endpoints are the percentage of days abstinent at four months using the Timeline Followback (TLFB) method, training satisfaction with a 9-point Likert scale, AUD symptoms with the Leeds Dependence Questionnaire (LDQ), and MiL with the Multidimensional Existential Meaning Scale (MEMS).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

1) It is expected that the percentage of days abstinent will be higher in both training interventions compared to the sham ApBM with religion-adapted ApBM having the biggest effect-size in this comparison. Also, it is expected that participants with the religion-adapted ApBM report more meaning in life.

2) We expect that the religion-adapted ApBM will lead to more training satisfaction after the last training session, and fewer AUD symptoms four months later compared to the other interventions.

Study design

Timetable investment

- Implementing research protocol in the organisation: 1 month (August 2021)
- Starting data collection (September 2021)
- Evaluating data collection of the first month (November 2021)
- Data collection at detoxification: 24 months (September 2021 to September 2023)
- Remaining data collection four month follow-up (September 2023 to December 2023)
- Analysis of data and writing article (June 2023 to December 2023)

Intervention

- (1) religion-adapted approach bias modification (ApBM)
- (2) Standard, non-religion ApBM
- (3) Sham ApBM

Contacts

Public

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Scientific

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Eligibility criteria

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

Recruitment

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

IPD sharing statement

Plan to share IPD: Undecided

Plan description

nvt

Ethics review

Positive opinion

Date: 05-10-2020

Application type: First submission

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
NTR-new	NL9014
Other	METc AMC : METC 2020_251

Study results

Summary results

nvt