Detoxification & Cognitive Bias Modification

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21035

Bron
NTR

Verkorte titel
DCBM

Aandoening

Alcohol Use Disorder

Ondersteuning

Primaire sponsor: De Hoop GGZ; Stichting tot Steun VCVGZ
Overige ondersteuning: De Hoop GGZ

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

(1) Percentage of days abstinent at four months follow-up

(2) Meaning in Life

Toelichting onderzoek

Achtergrond van het onderzoek

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 (TFLB) 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

De Hoop GGZ
Henk-Jan Seesink

0639863114

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

(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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-09-2021
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
nvt

Ethische beoordeling

Positief advies

Datum:	05-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9014
Ander register	METc AMC : METC 2020_251

Resultaten

Samenvatting resultaten
nvt