‘Do patients benefit from an Attentional Avoidance Training during an inpatient alcohol detoxification?’

No registrations found.

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

Summary

ID

NL-OMON28545

Source
NTR

Brief title
TBA

Health condition

alcohol use disorder

Sponsors and support

Primary sponsor: does not apply
Source(s) of monetary or material Support: does not apply

Intervention

Outcome measures

Primary outcome

The aim of the present study is to assess the effectiveness of an Alcohol Avoidance Training (AAT) and if the timing of the training is distinctive when applied during or after an inpatient detoxification.

Secondary outcome

Secondary outcome variables are the alcohol abstinence at three and six months post training, and alcohol craving rate and psychological complaints at two weeks, three and six months post training. Additionally, the expectations and evaluation (acceptability and feasibility) of the Alcohol AAT will be assessed.

Study description

Background summary

Alcohol addiction is a common disorder in the Netherlands, with 0.7% of the Dutch people meeting the criteria of an alcohol addiction (965.331 persons, 15 years or older, ICD-10, WHO, 2014).
Nowadays, the treatment of addiction in the Netherlands is primarily directed towards Cognitive Behavioural Therapy (CBT). This treatment targets the conscious cognitive processes which might be a possible reason of the limited success rates (Heitmann et.al., 2017). Dual process models became increasingly important in the explanation and treatment of addiction problems. It assumes that addictive behaviours are characterized by an imbalance between two independent but interacting information processing systems (Bechara, 2005, Stacy & Wiers, 2010, Manning, 2016), namely the impulsive and the reflective/executive system. The hypothetical imbalance between impulsive and reflective processes has been related to a number of cognitive biases (Wiers et al, 2013). These cognitive biases include an attentional bias (the tendency for alcohol-related cues in the environment to selectively capture attention) for alcohol-related stimuli (Field & Cox, 2008), a memory bias for the automatic activation of alcohol-related associations (Wiers, Van Woerden, Smulders, & De Jong, 2002), and a bias toward automatically activated action tendencies to approach alcohol (Palfai & Ostafin, 2003).
Cognitive Bias Modification (CBM) is a new training method to target these cognitive biases (Wiers et al., 2013). Wiers and colleagues developed the alcohol approach/avoidance task (Alcohol-AAT) to assess a potential bias in the action tendency to approach (versus avoid) alcohol stimuli (Wiers, Rinck, Dictus, & Van den Wildenberg, 2009). The use of alcohol-AAT in the treatment of alcohol-addicted participants has proven to be effective in reducing alcohol relapse in Germany and Australia (Manning et al., 2016, Eberl et al., 2013, Wiers et al, 2011). In his Australian study, Manning concludes that detoxification could be a potential critical time to modify approach bias (Manning et al., 2016). Patient detoxification may be an opportunity to capitalize on neural recovery via neurocognitive interventions that retrain cognitive biases (Manning et al., 2016). If confirmed, one reason could be that this early period of abstinence from alcohol is a particularly high-risk time for relapse. Studies reporting that 50 to 80% of addicted drinkers resume drinking following detoxification (Garbusow et al., 2014; Miller and Kavanagh, 2011; Sanghani et al., 2015), often within the first few days or weeks (De Wilde et al., 2014; Miller and Kavanagh, 2011). Summarizing: the results that are achieved in previous CBM studies with an AAT low-cost adjunctive treatment are promising, and more research is highly desirable.

Objective:
The aims of the present study are: (1) to assess for the first time in the Netherlands the effectiveness of an adjunctive Alcohol Avoidance Training (AAT) during inpatient alcohol detoxification to improve treatment outcomes. (2) To investigate for the first time in Europe if the timing of the training is distinctive comparing AAT during inpatient alcohol detoxification versus AAT after inpatient alcohol detoxification in terms of improving treatment outcomes. (3) The expectations, acceptability and feasibility of the AAT training will be investigated. If proven effective and feasible, this AAT training could be easily implemented as a low-cost adjunctive treatment to improve treatment outcomes for alcohol-dependent patients.

Study design:
A multicentre randomized controlled trial, with a repeated-measures design.

Study population:
All participants, both males and females, will be 18 years or older and will meet the Diagnostic and Statistical Manual-5 criteria for alcohol use disorder (American Psychiatric Association, 2013). They also have medical indication for an inpatient alcohol detoxification treatment (Treatment as Usual, TAU), which consisted of abstinence-oriented inpatient following the Dutch Multidisciplinary Treatment Guidelines (Dijkstra, 2017).

Intervention (if applicable):
After giving written informed consent, participants will be randomised and allocated to one of the four Alcohol Avoidance Training (AAT) during or after their inpatient alcohol detoxification (TAU):
a group of TAU + AAT during alcohol inpatient detoxification treatment
a group of TAU + placebo AAT during alcohol inpatient detoxification treatment
a group of TAU + AAT after alcohol inpatient detoxification treatment
a group of TAU + placebo AAT after alcohol inpatient detoxification treatment

Participants will receive five AAT sessions during the first three weeks of their inpatient detoxification treatment, or after week 3 to week 5 if they were allocated in the after inpatient detoxification condition. During the AAT training, participants are instructed to respond to certain types of images: with an approach movement (pulling a joystick) or with an avoidance movement (pushing a joystick). By pulling a joystick the size of the picture increases, while pushing the lever decreases the size of the picture (Wiers et al., 2009).

Main study parameters/endpoints:
The main outcome variable of this study will be alcohol abstinence at two-weeks. Outcomes will be assessed in a telephonic follow-up interview, there will be asked the same questions as in the computerised assessments before and after the AAT training sessions. Secondary outcome variables are the alcohol abstinence at three and six months post training, and alcohol craving rate and psychological complaints at two weeks, three and six months post training..

Assessments:
T0: start AAT: computerized assessment before first AAT training session.
T1: 2 weeks after AAT, participants will be asked to fill in two questionnaires
T2: 3 months after AAT training

T3: 6 months after AAT training

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
There are no risks associated with participating in the study. Participants are asked to complete the five AAT sessions during the first three weeks of the inpatient alcohol detoxification treatment or after. AAT takes a maximum of 20 minutes per session. In addition, they are asked to report their level of craving before and after each session (VAS, one question). Before the first AAT and at the follow-up measurements, they are asked to complete five questionnaires. Consisting of questions about substance use (4 questions), craving (5 questions), psychological complaints (21 questions), AAT expectations (4 questions) and AAT evaluation (acceptability and feasibility) (15 questions).

Study objective

We hypothesise that relapse of alcohol use will be reduced after two-weeks when participants participate in a AAT during an inpatient alcohol treatment compared to treatment as usual with a placebo AAT (sham training). We also assume that the effect will be larger when the AAT is offered during inpatient alcohol detoxification than when AAT is offered after inpatient alcohol detoxification. The main outcome variables of this study will be alcohol abstinence rate at two-weeks.

Study design

T0= start AAT
T1= 2 weeks after AAT
T2= 3 months after AAT
T3= 6 months after AAT

Intervention

Alcohol Avoidance Training

Contacts

Public
Novadic-Kentron
Nicolle van Mil

0612035572
Scientific
Novadic-Kentron
Nicolle van Mil

0612035572

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Informed consent
- 18 years or older
- meet the Diagnostic and Statistical Manual-5 criteria for alcohol use disorder (AUD, American Psychiatric Association, 2013)
- medical indication for inpatient alcohol detoxification treatment

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study, if there is any medical or psychiatric disorder or deficit in Dutch language proficiency that prohibits a good understanding of questions and instructions or the ability to take part in the AAT. Patients with a severe neurological disorder such as Korsakoff syndrome will be excluded.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	26-04-2021

Enrollment:	240
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	26-04-2021
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	NL9443
Other	Commissie Mensgebonden Onderzoek Regio Arnhem-Nijmegen : 2020-6311

Study results