The additive effects of combined brain stimulation and behavioural training on the treatment of alcohol dependence.

No registrations found.

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

Summary

ID

NL-OMON28847

Source
NTR

Brief title
CITAAT

Health condition

Alcohol dependent

Sponsors and support

Primary sponsor: University of Amsterdam
Source(s) of monetary or material Support: This research is supported by N.W.O. (Dutch Science Foundation) Research Talent Grant 406-11-203, and a grant from the European Foundation for Alcohol Research (ERAB, EA 1239).

Intervention

Outcome measures

Primary outcome

Clinical relevant outcome

Outcome name: Latency: time to relapse (more than 6 drinks), Timepoint: 3 months after treatment

Secondary outcome

These secondary outcome measurements can give us information on the possible underlying beneficial mechanisms of the training. The secondary outcome measurements are related to clinical success. The secondary measurements tap into different processes related to addiction; namely implicit information processing (the manipulated variable); subjective craving (a widely used measure, however also difficult to interpret sometimes in patients); physiological response towards alcohol (an indirect way of indexing automatic neural changes towards alcohol). The measurement of executive functions and mood serve as to possibly check for previously found effects of tDCS on mood and cognition and for moderator or mediator analyses.

Automatic avoidance bias towards alcohol: manipulation check (in approach/avoidance task (AAT) & transfer in approach avoidance associations (IAT)). Specific outcome on the same variable as the training, so we will be able to look at specific training effects. Increasing an avoidance bias has important beneficial consequences related to alcohol use.
Bias score = RT differences (median score for AAT, mean for IAT) for approach alcohol versus avoid alcohol trials (relative to soda trials). Timepoints: before training, after training

Craving (craving scores on short VAS scale and craving questionnaire (PACS)). Craving is predictive of relapse. These specific measures are relevant in comparing underlying group effects, since studies using tDCS have previously repetitively found effects on craving, however effects of AAT training on craving are less strong. It could be a way of differentiating between relevant clinical mechanisms between the three different groups.
The short VAS scales will give insight into direct effect of tDCS and AAT over time.
Timepoints: before and after each tDCS session.
PACS scores can indicate clinical relevant outcome of training overall. Timepoints: before training week 1, before training week 2, after training week 2.
Physiological response. (HR, HRV, GSR). Objective measurement of basic fitness and physiological response towards alcohol compared to non-alcohol drinks.
Timepoints: before training session 1, within 1 week after final training session.
Task: 5 minutes baseline rest, 5 minutes presentation of 30 non-alcohol pictures, 1 minute, 5 minutes presentation of 30 alcohol pictures, 1 minutes rest (order alcohol and non-alcohol is counterbalanced).
Measurements: Heart rate: beats per minute. Heart rate variability: RMSDD, HF-HRV (high frequency), LF-HRV (low frequency). Respiratory frequency: respirations per minute. Galvanic skin response: latency and amplitude of peripheral autonomic surface potential (PASP).

Executive functions (SOPT, Stroop, Delayed discounting): These cognitive functions may be influenced by tDCS and may be a relevant moderator and mediator of treatment effects.
Errors on a Self-ordered pointing task (SOPT, working memory), Timepoints: before training, after training block 1, after training block 2.
RT and errors on a classic computerised Stroop and an alcohol-Stroop (selective attention).
Timepoints: before training, after training.

Switch from lower immediate reward to longer reward (delayed discounting, decision making). Timepoints: before training, after training block 1, after training block 2.

Mood (VAS,BDI):
The short VAS scales will give insight into direct effect of tDCS over time. Timepoints: before and after each tDCS session.
Beck depression index (BDI) will indicate if mood has also changed due to tDCS and whether it might possibly mediate effects of tDCS. Timepoints: before and after training

Clinical:
Outcome name: Frequency: percentage of heavy drinking days (more than 6 drinks), Timepoint: 3 months after treatment

Outcome name: Latency: time to relapse since discharge clinic (more than 6 drinks), Timepoint: 1 year
Outcome name: Frequency: percentage of heavy drinking days since discharge clinic (more than 6 drinks), Timepoint: 1 year

Study description

Background summary

In two large studies alcohol avoidance training has been found to be effective in increasing treatment outcome for alcohol patients (Wiers et al., 2011; Eberl et al., 2012). It is hypothesized that stimulation of the prefrontal cortex with transcranial direct current stimulation (tDCS) may improve this training. TDCS is a technique with which a small electrical current can be sent through the cortex, this influences neuronal polarization and can increase plasticity; and thus can possibly enhance learning effects. Stimulating the dorsolateral prefrontal cortex has been found to reduce general and cue-elicited craving in alcoholic patients (Boggio et al., 2008). In a study researching smoking addiction 5 consecutive tDCS sessions were found to reduce craving and reduce the amount of cigarettes that were smoked (Boggio et al., 2009). In this study we want to investigate whether a combination of tDCS and alcohol avoidance training can have beneficial effects in treatment outcome. We want to see if these combined effects may surpass the effects of the training or tDCS on its own.

Study objective

TDCS will improve AAT training and improve clinical outcomes.
The combination of tDCS and AAT has effects on clinically relevant outcome measures

Study design

T1: pre-training assessment (within 1-5 weeks after entrance clinic)(psychological tasks and

physiological measurement on 2 different days)
T2: Short (psychological) assessment between training blocks (at start of 2nd training block)
T3: post-training assessment(psychological tasks and physiological measurement on 2 different days)
T4: Follow -up after 3 months
T5: Follow-up after 1 year

Intervention

1. Intervention: combined tDCS during CBM:
1 week with 4 sessions of 20 min. of 2 mA (real) tDCS during alcohol-AAT training, 1 week break, 1 week of 4 sessions of 30 s. of 2 mA (sham) tDCS during neutral video

2. Active control intervention: Only CBM
1 week with 4 sessions of 30 sec. of 2 mA (sham) tDCS during alcohol-AAT training, 1 week break, 1 week of 4 sessions 30 s. of 2 mA (sham) tDCS during neutral video

3. Active control intervention: isolated CBM and tDCS:
1 week with 4 sessions 30 sec. of 2 mA (sham) tDCS during alcohol-AAT training, 1 week break, 1 week of 4 sessions (real) tDCS during neutral video *

CBM = cognitive bias modification
tDCS = transcranial Direct Current Stimulation
alcohol-AAT = alcohol Approach/Avoidance Task

Contacts

Public
Weesperplein 4
T.E. Uyl, den
Amsterdam 1018 XA
The Netherlands
+31205256725
Scientific
Weesperplein 4
T.E. Uyl, den
Amsterdam 1018 XA
The Netherlands
+31205256725

Eligibility criteria

Inclusion criteria

Age: 18-65; Sex: M/F

Exclusion criteria

epilepsy, multiple sclerosis or other neurological illnesses, brain injury/infection, metal implants, pacemaker or other implanted apparatus, albino, pregnancy, skin condition.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-02-2014
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-03-2014
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	NL4327
NTR-old	NTR4475
Other	Duitse ethiek aanvraag : 10 R 35.08.12.000

Study results