The additive effects of combined brain stimulation and attentional retraining on the treatment of alcohol dependence

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23514

Source
NTR

Brief title
FUSTA

Health condition

alcohol dependence
alcohol verslaving

Sponsors and support

Primary sponsor: University of Amsterdam
Source(s) of monetary or material Support: NWO, Research Talent Grant, European Foundation for Alcohol Research

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 mechanisms of the training. The secondary outcome measurements are related to clinical success. They can 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. Attentional bias towards alcohol: manipulation check (in ABM assessment & transfer in Alcohol memory task & 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, dprime for memory, mean for IAT) for attend to 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 and AUQ)).

The short VAS scale will give insight into direct effect of tDCS and ABM over time. Timepoints: before and after each tDCS session.

PACS scores can indicate clinical relevant outcome of training overall. Timepoints: assessment 1 before training, assessment 2 after training.

AUQ will give insight into cue-induced craving. Timepoints: At the beginning and end of assessment 1 before training, and at the beginning and end of assessment 2 after training.

Physiological response. (HR, HRV, GSR). Objective measurement of basic fitness and physiological response towards alcohol compared to non-alcohol drinks. Timepoints: assessment 1 before training, assessment 2 after training. Task: 5 minutes baseline rest, 5 minutes presentation of 30 non-alcohol pictures, 5 minutes presentation of 30 alcohol pictures (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): Working memory may be influenced by tDCS and may be a relevant moderator and mediator of treatment effects. Errors on a Self-ordered pointing task (SOPT) Timepoints: assessment 1 before training, assessment 2 after training.

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, 6 months after treatment. Outcome name: Latency: time to relapse since discharge clinic (more than 6 drinks), Timepoint: 3 months after treatment, 6 months after treatment. Outcome name: Frequency: percentage of heavy drinking days since discharge clinic (more than 6 drinks), Timepoints: 3 months after treatment, 6 months after treatment.

Study description

Background summary

There is clinical data suggesting attentional bias modification (ABM) is a useful therapeutic approach (Schoenmakers et al. 2010). With an attentional bias modification paradigm patients are trained to avert their attention from alcohol. ABM for anxiety is likely to have a clinical value according to Macleod (2012). The DLPFC plays an important role in attention. The effects of tDCS on the DLPFC have been linked to effects on attention in several studies (e.g. Gladwin et al., 2012; Coffman et al., 2012 (enhancement of alerting attention)). Clarke et al. (2014) showed evidence that tDCS of the DLPFC can enhance the bias in a single session of an attentional bias modification training. In this study we want to investigate if tDCS can enhance effects of ABM training in alcoholic patients.

Important update [12-09-2016] regarding the relapse outcomes:
We had originally registered length of relapse as primary outcome and percentage of drinking days as secondary, following our previous study exactly (NTR4475). However, there was a mistake in this registration, percentage of drinking days turned out not to be a feasible measurement in the clinic and relapse occasion after 1 year was omitted (while this is a standard measure used in the clinic). This had come to our attention while in the process of publishing our previous study. We have not received the one year relapse data yet for this study. We would like register here that we intent to analyze it as primary outcome in the same manner as previous studies (den Uyl et al,. in press; Wiers et al., 2011, Eberl et al., 2013), meaning we would use relapse occurrence after 1 year as outcome in a logistic

regression with the same predictors as in the previous study.

Study objective

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

Study design

T1: pre-training assessment (within 1-5 weeks after entrance clinic)
T2: post-training assessment.
T3: Follow -up after 3 months
T4: follow-up after 6 months. T5: follow-up after 1 year.

Intervention

1. 4 sessions of 20 min 2 mA tDCS (real) + real ABM training.

2. 4 sessions of 1 min 2 mA tDCS (sham) + real ABM training.

3. 4 sessions of 20 min 2 mA tDCS (real) + placebo ABM training.

4. 4 sessions of 1 min 2 mA tDCS (sham) + placebo ABM training.

Contacts

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Eligibility criteria

Inclusion criteria

Age: 18-65,

Gender: 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:	Factorial
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-11-2014
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL4771
NTR-old	NTR5016
Other	Duitse ethiek aanvraag : V-067-15-SM-SM-tDCS-16102014

Study results