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

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23514

Bron
NTR

Verkorte titel
FUSTA

Aandoening

alcohol dependence
alcohol verslaving

Ondersteuning

Primaire sponsor: University of Amsterdam
Overige ondersteuning: NWO, Research Talent Grant, European Foundation for Alcohol Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age: 18-65,

Gender: M/F

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	04-11-2014
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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

Resultaten