

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

Gepubliceerd: 17-03-2014 Laatste bijgewerkt: 18-08-2022

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

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestart       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON28847

### Bron

NTR

### Verkorte titel

CITAAT

### Aandoening

Alcohol dependent

## Ondersteuning

**Primaire sponsor:** University of Amsterdam

**Overige ondersteuning:** 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).

## 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

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.

### Doel van het onderzoek

TDCS will improve AAT training and improve clinical outcomes.

The combination of tDCS and AAT has effects on clinically relevant outcome measures

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

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

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age: 18-65; Sex: 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: | Parallel              |
| Toewijzing:      | Gerandomiseerd        |
| Blinding:        | Dubbelblind           |
| Controle:        | Geneesmiddel          |

### Deelname

|                         |                      |
|-------------------------|----------------------|
| Nederland               |                      |
| Status:                 | Werving gestart      |
| (Verwachte) startdatum: | 24-02-2014           |
| Aantal proefpersonen:   | 90                   |
| Type:                   | Verwachte startdatum |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 17-03-2014       |
| 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        | NL4327                                     |
| NTR-old        | NTR4475                                    |
| Ander register | Duitse ethiek aanvraag : 10 R 35.08.12.000 |

## Resultaten