Stimulation Therapy in Miltary Veterans

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A tDCS intervention in veterans with anxiety and/or aggression problems increases the effects of an inhibitory control training

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27064

Bron
NTR

Verkorte titel
STIM

Aandoening

fear, anxiety, trauma, anger, aggression

Ondersteuning

Primaire sponsor: UMC Utrecht - Divisie Hersenen
Overige ondersteuning: Militaire GGZ

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Inhibitory control performance (stop signal reaction time, SSRT) on the stop signal task at the 5th training session.

Toelichting onderzoek

Achtergrond van het onderzoek

A substantial part of patients with trauma-related anxiety or aggression disorders does not sufficiently recover after psychotherapy. Recovery is likely impaired by difficulties with inhibitory control over (emotional) impulses. Amounting evidence shows positive effects of tDCS to the prefrontal cortex on psychiatric disorders like depression and drug- or alcohol dependence. Moreover, it has been shown that inhibitory control can be enhanced by applying transcranial direct current stimulation (tDCS) to the right inferior frontal gyrus.
The goal of the study is to test within an anxiety and aggression patient sample the effect of a tDCS intervention in combination with an inhibitory control training on inhibitory control performance, attention bias in response to threat and anxiety and aggression symptoms. Subjects undergo a 5-session tDCS intervention that takes place in a period of usual treatment. The tDCS (1.25 mA, 20 min.) electrodes are placed over the right inferior frontal gyrus (anodal) and over the left eyebrow (cathodal). Before and after the intervention inhibitory control performance an symptomatology are measured. Long-term measures of symptomatology are taken at 3 months and 12 months follow-ups.

Doel van het onderzoek

A tDCS intervention in veterans with anxiety and/or aggression problems increases the effects of an inhibitory control training

Onderzoeksopzet

T1. Pre-assessment: DSM Axis-I comorbodity, self-report symptomatology, inhibitory control performance.
Intervention. 5 training sessions with stop-signal task (SST).

T2. Post-assessment: self-report symptomatology, inhibitory control performance.

T3. follow-up after 3 months: self-report symptomatology.

T4. follow-up 12 months: self-report symptomatology

Onderzoeksproduct en/of interventie

TDCS (1.25 mA, 20 min.) increases neural excitability under the anodal electrode (here: attached to the scalp over the right inferior frontal gyrus, rIFG) and decreases neural excitability under the cathodal electrode (here: attached over the left eyebrow). This increases activation of the rIFG, a brain region strongly involved in inhibitory control. Subjects simultaneously receive tDCS and perform an inhibitory control (stop signal) task, to facilitate the effects of tDCS. Subjects receive 5 sessions of either real or sham tDCS + inhibitory control training.

Contactpersonen

Publiek

UMC Utrecht
S.G. Geuze
Heidelberglaan 100

Utrecht 3584 CX
The Netherlands
0302502000

Wetenschappelijk

UMC Utrecht
S.G. Geuze
Heidelberglaan 100

Utrecht 3584 CX
The Netherlands
0302502000

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Veteran of the Dutch Defense organization

- Age 18 – 50

- Presence of problems with aggression regulation according to criteria as described in (Coccaro, 2012) or any anxiety disorder according to DSM-IV criteria except for obsessive-compulsive disorder (OCD)

- Receive treatment for above-mentioned symptoms

- Provide written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Predominant major depressive disorder (MDD)

- Treatment for alcohol or drug dependence

- Severe psychiatric or neurological disorders, e.g., Parkinson’s disease.

- Serious head trauma or brain surgery

- Large or ferromagnetic metal parts in the head (except for a dental wire)

- Implanted cardiac pacemaker or neurostimulator

- Pregnancy

- Concurrent or recent (within previous month) participation in a neuromodulation / neurostimulation (e.g., tDCS, TMS) experiment.

- Skin damage or diseases at intended electrode sites (tDCS)

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-05-2016
Aantal proefpersonen:	96
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-05-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46862
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5709
NTR-old	NTR5862
CCMO	NL56137.041.16
OMON	NL-OMON46862

Resultaten