Stimulation Therapy in Miltary Veterans

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27064

Source
NTR

Brief title
STIM

Health condition

fear, anxiety, trauma, anger, aggression

Sponsors and support

Primary sponsor: UMC Utrecht - Divisie Hersenen
Source(s) of monetary or material Support: Militaire GGZ

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Short-term:

- Pre- to post changes on symptomatology (PTSD, anxiety, aggression/anger, depression, impulsivity and therapy progress)

- Pre- to post changes on inhibitory control (emotional Go/NoGo task, implicit association test).

- Post-intervention attentional threat avoidance (dot-probe task)

Long-term:

- Changes in symptomatology on 3-month and 12-month follow-up.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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.

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2016
Enrollment:	96
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-05-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46862
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results