Stimulation Therapy in Military Veterans

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To test within an anxiety and aggression patient sample the effect of a tDCS intervention on (i) task-specific inhibitory control, and (ii) threat and implicit inhibitory control, attention bias and anxiety and aggression symptom reduction in a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON46862

Source
ToetsingOnline

Brief title
STIM

Condition

- Anxiety disorders and symptoms

Synonym
post-traumatic stress disorder; anxiety disorder; intermittent explosive disorder; impulsive aggression;

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: militaire GGZ;ministerie van Defensie

Intervention

Keyword: aggression, anxiety, inhibition, tDCS

Outcome measures

Primary outcome

The main study parameter is the pre-to post-intervention change in inhibitory control on the training task (stop-signal task).

Secondary outcome

Second, we aim to test the pre-to post-intervention changes in symptoms related to anxiety and aggression, threat-related (emotional Go/No-Go task) and implicit inhibitory control (implicit association task). Additionally we look at post-intervention attentional threat avoidance (dot-probe task). Finally, we assess symptom reduction at 3 and 12 months 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. It has been shown that inhibitory control can be enhanced by applying transcranial direct current stimulation (tDCS) to the prefrontal cortex. Moreover, amounting evidence shows positive effects of tDCS to the prefrontal cortex on depression and craving symptoms. These findings suggest a potential therapeutic or treatment facilitating effect of tDCS for patients with anxiety or aggression problems.

Study objective

To test within an anxiety and aggression patient sample the effect of a tDCS intervention on (i) task-specific inhibitory control, and (ii) threat and implicit inhibitory control, attention bias and anxiety and aggression symptom reduction in a period of usual treatment.

Study design

This is a double-blind placebo-controlled intervention study with an experimental group (active tDCS) and a control group (sham tDCS). Subjects undergo a 5-session intervention. Pre- and post-intervention assessments and follow-ups provide insight in effects over time on inhibitory control (tasks) and PTSD, anxiety, aggression and mood symptoms (questionnaires).

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.

Study burden and risks

The total number of separate assessment time points is 10. Because pre- and post-assessments and follow-ups are completed online, each subject has 6 visits in total (1 intake, 5 tDCS sessions). Subjects continue with usual treatment during the study period. The application of tDCS in this study is considered safe. Common side-effects of tDCS are minor (e.g. a light itching sensation or skin irritation under the electrode).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Dutch military personnel
- Age 18 - 60 years
- 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)
- Alcohol or drug dependence
- Severe psychiatric or neurological disorders, e.g., Parkinson*s disease.
- Serious head trauma or brain surgery (N.B. TBI without brain damage or skull damage is not a reason for exclusion)
- 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2016
Enrollment:	96
Type:	Actual

Medical products/devices used

Generic name:	non-invasive brain stimulation: transcranial direct current stimulation (tDCS)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-04-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	20-10-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-12-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-12-2018
Application type:	Amendment

Review commission: METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27064
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL56137.041.16
OMON	NL-OMON27064

Study results

Date completed: 10-10-2020

Results posted: 29-07-2021

Actual enrolment: 96

First publication
26-07-2021