

Brain Stimulation for Mental Control

No registrations found.

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

Summary

ID

NL-OMON26132

Source

Nationaal Trial Register

Brief title

CONTROL

Health condition

Prevention of PTSD, anxiety, impulsive aggression

Sponsors and support

Primary sponsor: UMC Utrecht - Divisie Hersenen

Source(s) of monetary or material Support: Militaire GGZ / Dutch Ministry of Defence

Intervention

Outcome measures

Primary outcome

Reactions to threat of shock in the Neutral, Predictable, Unpredictable Threat test (eye-blink startle, subjective fear ratings)

Secondary outcome

- Working memory (N-back task) performance in a threat context;
- Inhibitory control (Go/NoGo task) performance in a threat context;

- EEG resting-state activity and event-related potentials during above mentioned task performance.

Study description

Background summary

Military personnel need good self-regulation capacity to maintain adequate operational performance in situations of threat and prevent the risk on stress-related mental-health problems. Self-regulation skills could be temporarily facilitated by applying transcranial direct current stimulation (tDCS) to the DLPFC, probably through enhancing DLPFC-dependent executive functions such as working memory and inhibitory control. Yet, the potential longer-lasting benefits for self-regulation capacity under threat of a tDCS intervention have not yet been studied, and the neural underpinnings of these effects remain insufficiently understood.

The goal of this study is to investigate if a 3-session tDCS intervention targeting the DLPFC combined with working memory training improves regulation of reactions to threat. Second, we aim to verify if this intervention improves executive functioning in threat contexts, and to explore tDCS-induced modulations in neural activity linked to cognitive regulation and emotion.

This study is carried out among healthy Dutch military personnel.

Study objective

A combined tDCS-working memory intervention strengthens self-regulation under threat via effects on DLPFC-linked neural activity

Study design

T0. Baseline measures of (i) reactions to threat of shock, (ii) inhibitory control, (iii) EEG.

T1-T3. tDCS sessions with measures of (i) working memory training performance and (ii) emotional state and tDCS side effects

T4. Post-intervention measures of (i) reactions to threat of shock, (ii) inhibitory control, (iii) working memory, (iv) EEG.

Intervention

A tDCS intervention with an active tDCS group and a placebo group (sham tDCS), consisting of 3 repeated sessions targeting the DLPFC. TDCS is applied with an intensity of 2.0 mA over a 3x3 cm anode (on 10/20 EEG location F4) and 5x7 cm cathode (behind Cz) for 20 minutes, and is combined with a working memory (N-Back) training in a threat context.

Contacts

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Eligibility criteria

Inclusion criteria

- 18-60 years of age
- Uncorrected normal hearing
- Provide written informed consent

Exclusion criteria

- Alcohol or drug dependence
- Use of illicit drugs or psychoactive medication within the past two weeks
- Having a current psychiatric diagnosis
- Having a current or previous neurological disorder, e.g., epilepsy, Parkinson's disease.
- Serious head trauma or brain surgery (N.B. TBI without brain damage or skull damage is no 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 or 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):	03-02-2020
Enrollment:	62
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	10-06-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48232
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8698
CCMO	NL70493.041.19
OMON	NL-OMON48232

Study results