

Brain Stimulation for Mental Control

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

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

Samenvatting

ID

NL-OMON26132

Bron

Nationaal Trial Register

Verkorte titel

CONTROL

Aandoening

Prevention of PTSD, anxiety, impulsive aggression

Ondersteuning

Primaire sponsor: UMC Utrecht - Divisie Hersenen

Overige ondersteuning: Militaire GGZ / Dutch Ministry of Defence

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Militaire GGZ / UMC Utrecht
Fenne Smits

030 250 2590

Wetenschappelijk

Militaire GGZ / UMC Utrecht
Fenne Smits

030 250 2590

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	03-02-2020
Aantal proefpersonen:	62
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:	10-06-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48232
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten