Neuromodulation as an intervention to improve empathic abilities and reduce violent behavior in forensic offenders

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21270

Source
NTR

Brief title
TDCS TO INCREASE EMPATHIC ABILITIES AND REDUCE VIOLENCE

Health condition

Substance use, lack of empathy, violent behavior

Sponsors and support

Primary sponsor: Erasmus University Rotterdam
Source(s) of monetary or material Support: Kwaliteit Forensische Zorg (KFZ), Stichting Volksbond Rotterdam en Stichting Koningsheide.

Intervention

Outcome measures

Primary outcome

To increase empathic abilities and reduce violent behavior in offenders with substance abuse problems through stimulation with tDCS.

Secondary outcome

A decrease in craving for cocaine and alcohol in substance use offenders.

A change in electrophysiological responding in the brain from pre- to postintervention.

Follow up after six months.

Study description

Background summary

Rationale:

Substance abuse problems have an important relationship with criminal behavior. These problems occur in 50-75% of the offenders, and cost the community about 600 milliard due to costs of crime, work-related problems and especially (mental) healthcare. Problems that substance abuse patients cause are an enormous burden to the community (financial and safety). Previous research has found that substance abuse, especially alcohol and cocaine, are related to (violent) criminal behavior. Money invested in treatment may lead to a large reduction in the costs associated with substance abuse.

Nevertheless, current interventions seem insufficient in treatment of substance abuse in forensic mental health care and are not sufficient enough to reduce violence risk, 66% of the patients reoffend. This could be due to the fact that problem is caused by a complex medical-psychiatric disorder, occurring within a poor motivated population, in which the prolonged usage of substances has led to functional and structural changes in the brain.
Recent studies show that changes in the brain areas related to less empathic abilities (i.e. the Ventromedial Prefrontal Cortex (vmPFC) plays an important role in violent behavior in abusers of alcohol and cocaine.

According to the recent models violent behavior is supposed to be inhibited by empathy. Individuals with less empathic abilities may be less susceptible and motivated to inhibit violent behavior, which causes a higher risk of violence.
Recent neuroscientific research shows that modulating (stimulation or inhibition) of certain brain areas, such as the neurostimulation technique Transcranial Direct Current Stimulation (tDCS), could be a promising new intervention for substance abuse and to reduce violent behavior.

Objective: The aim of this study is to investigate the effectiveness of tDCS in increasing empathy and reducing violent behavior in offenders with substance abuse problems. Through stimulation (and/or inhibiting) certain areas of the brain, tDCS causes a change in the

function of the brain, due to an increase in susceptibility to generate and facilitate brain related electrical impulses. This susceptibility is achieved through repeatedly offer brain stimulation and this causes ‘learning’ of the brain cells. Functions of the brain damaged and changed by the substance abuse will be recovered.

Study design: The design will be a double-blind, placebo-controlled study.

Study population: A total sample of 50 male forensic addicted patients (25 experimental + 25 sham stimulation) between the age of 18-60 years will be tested in a double-blind placebo-controlled study.
Intervention (if applicable): 25 patients will receive the experimental condition + treatment as usual (TAU) and the other 25 patients will receive a sham condition (placebo) + TAU.

Main study parameters/endpoints: The study investigates the effectiveness of tDCS to change the learning process of the brain cells through electrical stimulation and with that to increase empathic abilities and reduce violence risk in offenders with substance abuse problems. To test the effect of the intervention on the level of empathy, patients will perform a passive viewing task in which they see victims of aggression and rate the degree of empathy they feel for each of the pictures after the passive viewing part of the task.

To test the effect of the intervention on aggression, the Point Subtraction Aggression Paradigm (PSAP) will be used. As a standard for effectiveness of the reduction of violent behavior before and after the tDCS intervention next to the aggression task (PSAP-task) the results of the K-items of the HKT-R risk assessment tool before and after the intervention will be compared.
To measure the degree of brain changes in empathy caused by the intervention, electro-encephalography (EEG) will be used. The expectation is that patients who receive tDCS intervention will show higher amplitude in EEG towards the pictures of the victims after the intervention and compared patients who have received the sham-condition.

Study objective

The intervention with Transcranial Direct Current Stimulation (tDCS) on the Ventromedial Prefrontal Cortex (vmPFC) in comparison with the treatment as usual will improve empathic abilities and reduce violent behavior in forensic substance use offenders.

Study design

Measurements:

-Empathy will be measured with the 'Passive Viewing Empathy Task'

-Violent behavior will be measured with the 'Point Substraction Aggression Paradigm'.

-Electrophysiological changes will be measured with Electroencephalography (EEG).

Questionnaires:

-Psychopathic traits will be assessed using the Dutch short version of the SRP-SF. (Self Report Psychopathy Scale ;SRP-SF)

- Reactive and Proactive Aggression will be measured using the Dutch version of the Reactive and Proactive AggressionQuestionnaire (RPQ).

Empathy is measured Interpersonal Reactivity Index (IRI) [81]

Empathy will be measured using the Dutch IRI

 Toronto Alexithymia Scale (TAS-20) [82] Aggression will be measured using the Dutch RPQ.

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tDCS as intervention for violence risk

 Behavioral Impulsivity Scale (BISS11) [89] Impulsivity will be measured using the Dutch BISS11

 Risky, Impulsive, and Self-Destructive Behavior Questionnaire (RISQ) [83] Risky and Impulsive behavior will be measured using the Dutch version of the RISQ

 Alcohol Use Disorders Identification Test (AUDIT) [79] Alcohol use will be measured using the Dutch version of the AUDIT

 Drug Use Disorder Identification Test (DUDIT) [84] Drug use will be measured using the Dutch version of the DUDIT

 Obsessive Compulsive Drug Use Scale (OC-DUS-versie Cocaïne) [85] Drug craving will be measured using the Dutch version of the OC-DUS.

 Obsessive Compulsive Drinking Scale (OCDS) [86]

Alcohol craving will be measured using the Dutch version of the OCDS

Intervention

tDCS will be administered with a CE-certified neurostimulator (StarStim-8, NeuroElectrics) following the protocol used by Geniole, MacDonell & McCormick (2016). The device will be preprogrammed for stimulation with 2mA during 20 minutes (experimental conditions), or with 2 mA during 30 seconds (sham condition). It is possible to program the device for each

participant, ensuring that the participant and experimenter are blinded for experimental condition.
The treatment under study is a tDCS intervention. The experimental treatment is a 20 minutes tDCS session, two times a day for 5 days (10 sessions per participant). HD-tDCS stimulation will be applied over the VMPFC.

Sham condition is the same as the experimental condition with the exception that there will only be a ramp up of the electrical stimulation to mimic the sensation of the stimulation.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

-Male

-Age 18-60

-Good understanding of the Dutch language

-Diagnosed with an alcohol and/or cocaine SUD according to the DSM-5

-Patients have to be abstinent

-Index offence in violence category

Exclusion criteria

-Major neurological conditions (e.g. traumatic brain injury).

-Major mental disorders (i.e. major depression, psychotic symptoms)

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2019
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-01-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46791
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7459
NTR-old	NTR7701
CCMO	NL65209.078.18
OMON	NL-OMON46791

Study results