The effects of repetitive tDCS on relapse in cocaine addiction: An ecological momentary assessment (EMA) study

Published: 20-09-2016
Last updated: 16-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43214

Source
ToetsingOnline

Brief title
Effects of tDCS in cocaine relapse

Condition

- Other condition

Synonym
Drug dependence, Substance abuse

Health condition

Verslaving

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus Universiteit Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Addiction, EMA, Relapse, tDCS

Outcome measures

Primary outcome

Relapse probability in cocaine addicted patients as measured by means of EMA after twice daily sessions of bilateral tDCS (left cathodal/right anodal) over the DLPFC for five consecutive days. The primary study outcome is number of relapse days at three months follow-up.

In addition, number of relapse days after one week, craving, temptations and cognitive control will be assessed as possible predictors of relapse days at 3 months follow-up. Craving will be measured at the same moments in time as relapse, by means of five single EMA items. Cognitive control will be determined by inhibitory control and risky decision making. Inhibitory control will be measured by performance on NoGo trials in the Go/NoGo task. Mean number of pumps on the BART task will represent risk-taking.

Secondary outcome

The following control variables will be assessed: positive- and negative affect, alcohol/ drug use, life satisfaction, amount of drug use in the past month, starting age of using drugs and current age.

Study description

Background summary

Neurobiological substrates that are related to specific cognitive problems, like the Prefrontal Cortex (PFC), seem to play an important role in the aetiology and maintenance of SUD (Franken & van de Wetering, 2015). Consequently, it is thought that modulation of brain activity related to these cognitive problems would reduce addiction-related symptoms. Transcranial Direct Current Stimulation (tDCS) is an electrical brain stimulation method that has been explored in this area of interest. Previous studies suggest that repetitive bilateral tDCS (left cathodal/right anodal) over the DLPFC is the most effective treatment intervention in addiction. For example, Klauss and colleagues (2014) found that 10 twice daily sessions of bilateral DLPFC tDCS (left cathodal/ right anodal) reduced relapse probability for up to six months in alcohol dependent patients. However, craving measured by retrospective self-reports did not diminish. In contrast to Batista and colleagues (2015) who did find diminished craving after 5 once daily sessions of bilateral tDCS (left cathodal/ right anodal) in crack-cocaine addicted patients.
The effects of this tDCS method on relapse have not yet been studied in cocaine addiction, despite the need for treatments reducing the high frequency of relapses in cocaine addicted patients. Twice daily sessions seem to produce long-term effects (Monte-Silva et al., 2013; Klauss et al., 2014) and would therefore be particularly interesting to study in cocaine addiction.
It is expected that this particular tDCS method (bilateral (left cathodal/right anodal) over the DLPFC twice daily for 5 consecutive days) will reduce relapse probability. Furtermore, we expect this therapeutic effect to be associated with diminished craving and enhanced cognitive control. Craving, temptations and relapse, will be explored by means of Ecological Momentary Assessment (EMA). The mixed results in previous studies of tDCS on craving may be explained by the fact that craving in addiction is a momentary phenomenon which is difficult to reliably measure with more traditional methods like retrospective self-reports (Serre, Fatseas, Swendsen, & Auriacombe, 2015). EMA offers a reliable and ecologically valid alternative, since this method makes it possible to repeatedly measure craving at random moments of the day by means of questionnaires via a mobile device.

Study objective

The aim of this study is to explore the effectiveness of repetitive bilateral tDCS (left cathodal/right anodal) over the DLPFC on relapse in cocaine addicts. Craving, temptations and cognitive control functioning will be assessed as predictors of relapse to explore the working mechanism behind the therapeutic effects of tDCS in addiction. It is expected that the tDCS intervention will reduce relapse compared to a control condition (sham tDCS). In addition we expect diminished craving and enhanced cognitive control functioning in the

tDCS group.

Study design

The design of the proposed experiment is a double-blind randomized placebo-controlled trial. Eighty cocaine addicted patients will be randomly assigned to two conditions, namely tDCS or sham (placebo). Both the researcher as well as the patient will be blinded of the condition they are in (see paragraph 7.2 research protocol).

During and after this two week period, participants have the possibility to indicate temptations (TA) and relapse for up to three months. A weekly reminder will be send to remind them of this possibility. Participants are asked to return after these three months to fill in the same questionnaires and perform the same psychological tasks as before, to measure the lasting effect of tDCS.

Intervention

One group will receive bilateral tDCS (left cathodal/right anodal) over the DLPFC. The stimulation will take place two times daily for 13 minutes with a rest interval of 20 minutes for five consecutive days. The stimulator will induce tDCS with an intensity of 2.0 mA. The control group receives sham, for which the stimulator will be gradually turned off after 30 seconds.

Study burden and risks

Participants will receive real-tDCS or sham twice daily for 13 min with an interval of 20 min for five consecutive days. At baseline (before the tDCS intervention) and a day after five days of treatment participants complete a number of questionnaires and psychological tasks. In addition, participants respond to a total of 15 single item questions about craving, affect, and relapse first at baseline and then three times daily on a quasi-random basis by means of EMA during the intervention period.
During and after this two week period, participants have the possibility to indicate temptations (TA) and relapse for up to three months. A weekly reminder will be send to remind them of this possibility. Participants are asked to return after these three months to fill in the same questionnaires and perform the same psychological tasks as before, to measure the lasting effect of tDCS.

Adverse effects of tDCS may be tingling and itching sensations under the electrodes, headache, and tiredness (p.8 research protocol). However, customarily applied tDCS protocols do not induce structural or functional damage, and are well tolerated. Participants may however benefit from the tDCS treatment.

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

Aged between 18 and 65 years
Meeting the DSM-V criteria for cocaine dependence
The ability to speak, read, and write in Dutch at an eight-grade literacy level
No severe withdrawal signs or symptoms at baseline

Exclusion criteria

- Indications of severe psychopathology (psychosis, severe mood disorder) as assessed by a physician;
- A diagnosis of epilepsy, convulsions or delirium tremens during abstinence of cocaine;
- The intake of medications for psychiatric conditions;

- Any contraindication for electrical brain stimulation procedures such as electronic implants or metal implants;
- Pregnancy or breast-feeding.

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:	Pending
Start date (anticipated):	01-09-2016
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-09-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL57262.078.16