The longitudinal effects of repetitive tDCS on cigarette consumption: An ecological momentary assessment (EMA) study

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The primary objective of the study is to explore the effect of repetitive tDCS (left cathodal/right anodal) on mean daily cigarette consumption three months after tDCS by means of ecological momentary assessments (EMAs).To examine the course of...

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

Summary

ID

NL-OMON43108

Source
ToetsingOnline

Brief title
Effects of tDCS on cigarette consumption

Condition

- Other condition

Synonym
Nicotine addiction, Tobacco use

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: EMA, ERPs, Smoking, tDCS

Outcome measures

Primary outcome

Mean number of smoked cigarettes a daythree months after tDCS treatment, as measured by means of EMA for one week

Mean craving a day three months after tDCS treatment, as measured by means of EMA for one week

Behavioral and electrophysiological responses to risk-taking and inhibitory control directly before and after the tDCS treatment week. These measures of inhibitory control can be assessed during NoGo trials on the Go/NoGo task. Mean number of pumps on the BART task will represent risk-taking. Positive and negative feedback during the BART task can be used to study electrophysiological responses (See paragraph 8.3 page 17 of protocol).

Number of cigarettes (and craving) per day starting on the first tDCS day until one week after the last tDCS intervention (total of 14 days) to study the course of cigarette consumption during and after tDCS.

Secondary outcome

Levels of carbon monoxide on the days that subjects are visiting the Erasmus

Behaviors Lab, to control for EMA logged number of cigarettes.

Furthermore, 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

Tobacco use leads to the largest number of preventable deaths world-wide and costs billions of dollars each year. Currently available treatments such as nicotine supplements seem to have limited efficacy, since tobacco users who try to quit smoking often fail in doing so. Improvement of treatment interventions in nicotine addiction may be accomplished by focusing on the modulation of neuronal activity, since substance use disorders (SUDs) are associated with neurocognitive aberrations.

The dorsolateral prefrontal cortex (dlPFC) has been a target area of interest in non-invasive neuromodulation studies among tobacco users and other substances of abuse. Transcranial direct current stimulation (tDCS), a non-invasive neuromodulation technique, diminished cue-induced craving in smokers when the anode was placed over the right dlPFC. Furthermore, it was found that a single tDCS session could increase the time till smoking the first cigarette after the intervention. More interesting however, is whether actual cigarette consumption decreases due to tDCS. Only one study has focused on this area of interest. They found that after five consecutive days of tDCS cigarette smoking had decreased according to subject*s self-reported measures, but not when using a carbon monoxide monitor.

These mixed findings may be caused by bias in subjects* responses to retrospective self-reports. To overcome this problem, the current study aims to further explore the effects of repetitive tDCS on cigarette consumption by means of ecological momentary assessments (EMAs). EMA makes it possible to repeatedly measure craving and cigarette use at random moments of the day, and seems to result in more reliable and representative measures of craving and

drug use compared to retrospective self-reports. Consequently, EMA offers an ecologically valid research tool in exploring the therapeutic effects of tDCS.

To optimize the therapeutic effects of tDCS, the interventions will consist of twice daily sessions of bilateral tDCS over the dlPFC (left cathodal / right anodal) for three days. Previous studies suggest that repetitive tDCS over the dlPFC (left cathodal/right anodal) is the most effective treatment intervention in addiction. Furthermore, twice daily sessions seem to produce long-term effects and would therefore be particularly interesting to study in nicotine addiction.

The second aim of the study is to explore the working mechanism behind the therapeutic effects of repetitive tDCS in nicotine addiction. It is suggested that tDCS over the dlPFC modulates the activity in this brain area. Decreased brain activity in the dlPFC is related to nicotine addiction, and this decrease is believed to be associated with diminished cognitive control. For example, smokers show aberrations in inhibitory control and risk-taking compared to non-smokers. Risk-taking seems to be reward-sensitive, and so it is suggested that when experiencing the urge to use drugs, an unbalance between inhibitory control and reward processing may lead to the actual decision to use tobacco. To examine this hypothesis, behavioural and electrophysiological measures of inhibitory control and risk-taking will be assessed. It is expected that tDCS will enhance cognitive control functioning, leading to less craving and cigarette consumption.

(References see page 8 and 9 in research protocol)

Study objective

The primary objective of the study is to explore the effect of repetitive tDCS (left cathodal/right anodal) on mean daily cigarette consumption three months after tDCS by means of ecological momentary assessments (EMAs).

To examine the course of cigarette consumption after repetitive tDCS, starting on the first treatment day until one week after the last tDCS intervention (total of 14 days).

The secondary objective is to explore the working mechanism behind the therapeutic effects of repetitive tDCS in nicotine addiction by means of craving, and behavioural and electrophysiological responses of risk-taking and inhibitory control.

Study design

The design of the proposed experiment is a double-blind randomized placebo-controlled trial. Eighty smokers 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.

Participants will receive tDCS for three days in one week. During these days, participants receive tDCS or sham twice daily for 13 minutes with an interval of 20 min. Also, on the first treatment day and the day after the treatment week, participants complete a number of questionnaires, and perform two psychological tasks (BART task and the Go/NoGo task). During these tasks event-related potentials will be recorded by means of EEG. After three months, participants are asked to return to fill out the same questionnaires and perform the same psychological tasks as before, to measure the lasting effect of tDCS. During this last session, event-related potentials will also be recorded. Also, carbon monoxide levels will be measured on all days where subjects perform the tasks.

Furthermore, for three weeks, starting the week before tDCS treatment, participants are asked to log every cigarette before they smoke one. During these weeks, participants also complete EMA questionnaires about cigarette consumption, craving, and affect that will take approximately 10 minutes. The EMA questionnaire will be presented four times daily on a quasi-random basis. Finally, during end-of-day and morning assessments participants have the possibility to indicate any missed cigarettes. At three months follow-up, participants are asked to undergo the same EMA procedure for one more week, to study the lasting effects of tDCS.

Intervention

One group receives 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 three days. At baseline (before the tDCS intervention) and a day after the days of treatment participants complete a number of questionnaires and psychological tasks during which event-related potentials will be recorded. Furthermore, after three months participants are asked to return to the Erasmus Behavioral Lab for the same procedure. As a consequence, the experiment takes two hours on the first treatment day, and one hour on the other 4 days.

Furthermore, for three weeks, starting the week before tDCS treatment, participants are asked to log every cigarette before they smoke one. During

these weeks, participants also complete EMA questionnaires about cigarette consumption, craving, and affect that will take approximately 10 minutes. The EMA questionnaire will be presented four times daily on a quasi-random basis. Finally, during end-of-day and morning assessments participants have the possibility to indicate any missed cigarettes. At three months follow-up, participants are asked to undergo the same EMA procedure for one more week, to study the lasting effects of tDCS.

Adverse effects of tDCS may be tingling and itching sensations under the electrodes, headache, and tiredness.. However, customarily applied tDCS protocols do not induce structural or functional damage, and are well tolerated. Participants may however benefit from the tDCS treatment in reducing craving and cigarette consumption.

Contacts

Public
Erasmus Universiteit Rotterdam

Burgemeester Oudlaan 50
Rotterdam 3062 PA
NL
Scientific
Erasmus Universiteit Rotterdam

Burgemeester Oudlaan 50
Rotterdam 3062 PA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Between 18 and 65 years old
- Currently smoking 10 or more cigarettes a day
- The ability to speak, read, and write in Dutch at an eight-grade literacy level

Exclusion criteria

- The current abuse of a substance other than nicotine or caffeine
- History of neurological or psychiatric disorders
- Any contraindication for electrical brain stimulation procedures such as electronic implants or metal implants
- Pregnancy or breast-feeding
- In the process of stopping smoking

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):	04-09-2016
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO Date:	30-08-2016
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	NL58190.078.16