Neurocognitive predictors of treatment outcome in cocaine patients: the role of cognitive control

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON33279

Source
ToetsingOnline

Brief title
Cognitive control in cocaine addiction

Condition

- Other condition
- Impulse control disorders NEC

Synonym
cocaine addiction, cocaine dependence

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: attentional control, cocaine dependence, error processing, relapse

Outcome measures

Primary outcome

Comparing the error-processing and attentional control of abstinent cocaine dependent patients (during their first week in a detoxification department) to healthy controls.

Secondary outcome

The predictive value of the ERN component and error rates (as measured with ERPs and behavioral errors during an Eriksen Flanker task) and the predictive value of attentional control (as measured with the eye-tracker and fMRI).

Study description

Background summary

One of the major challenges in substance dependence treatment is to improve treatment outcome. Dropout rates in detoxification clinics for illicit drugs are about 50% within the first month. Currently, there is insufficient knowledge about the factors influencing this outcome. Recent advances in clinical and cognitive neuroscience might give us better measures to predict treatment outcome. In the present study we will focus on the role of cognitive control. More specifically, we propose to examine two indices of (neuro)cognitive control associated with cocaine addiction: reduced error processing and reduced attentional control. We will measure the neurophysiological correlates of these mechanisms using Event Related Potentials (ERPs; error processing) and eye-tracker (attentional control). More specifically, we are interested in a decreased Error-Related Negativity (ERN) as neurophysiological indices of reduced error-processing and increased visual

fixation to drug related stimuli as behavioral measure of reduced attentional control. In order to assess these (neuro)cognitive parameters participants will carry out an Eriksen flanker task (for the error-processing study) and a picture task with drug related and neutral stimuli (for the attentional control task) during the first week of their detoxification.
In addition, participants will perform a cocaine Stroop task in the fMRI scanner. We will examine differences in brain activity between cocaine dependent patients and controls on the Stroop task, an index of attentional control in the presence of cocaine cues.

Study objective

The main goal of the study is to examine the predictive value for treatment outcome of
neurophysiological indices of two aspects of cognitive control in abstinent cocaine dependent patients: Error-processing and attentional control (respectively assessed with ERPs, eye-tracker and fMRI).

Study design

All patients will be recruited from the detoxification department of the addiction treatment center BoumanGGZ in Rotterdam. The participants will be assessed at Erasmus University Rotterdam, department of Psychology (ERP and eye-tracker assessment) and Erasmus MC (fMRI assessment). We will collect the baseline variables race, age, education, gender, medical problems (Addiction Severity Index; ASI), and psychopathology (ASI), and drug use variable (ASI).
In addition, in order to assess the actual decreased Error-Related Negativity and increased visual fixation/attention to drug related stimuli we will compare the baseline findings to healthy control groups. Most importantly, after one month we will assess whether patients completed the detoxification treatment (treatment compliance) and after 3 months we will assess treatment outcome (relapse rates) by means of a structured interview and urine analysis. We will examine the predictive value of the neurophysiological and behavioral indices of cognitive control for both treatment compliance and relapse rates.

Study burden and risks

fMRI is an invasive measurement. The apparatus that is being used consists (among other things) of a strong magnet. This magnet pulls metal objects. Therefore it is important that during participation there are no metal objects in and around the human body. The participant will be alerted about this.

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

age 18-65; meet the DSM-IV criteria for cocaine dependence; can read, speak, and write in Dutch at an eight-grade literacy level.

Exclusion criteria

indications of severe psychopathology; self-reported non-corrected defective vision; pregnant or breastfeeding.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2009
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	22-04-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	28-09-2009
Application type:	Amendment
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	NL26442.078.09