Neurofeedback: An effective treatment for impulsivity and addiction in forensic psychiatric patients?

No registrations found.

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

Summary

ID

NL-OMON24938

Source
Nationaal Trial Register

Health condition

Forensic inpatient treatment, substance abuse disorder, neurofeedback, impulsivity, cued Go/No-Go task, BIS-11, Desire for alcohol questionnaire (DAQ).

Forensische psychiatrie, TBS, middelenafhankelijkheid, verslaving, neurofeedback, impulsiviteit, cued Go/No-Go taak, BIS-11, DAQ (DAQ).

Sponsors and support

Primary sponsor: FPC Dr. S. van Mesdag, Helperlinie 2, 9722 AZ Groningen
University of Tilburg, Warandelaan 2, 5037 AB Tilburg
FPC De Kijvelanden, Kijvelandsekade 1, 3172 AB Portugaal.
Source(s) of monetary or material Support: FPC Dr. S. van Mesdag
University of Tilburg

Intervention

Outcome measures

Primary outcome

Resting-state EEG

Participants will undergo a 21-channel EEG with Nexus-32 hardware and Biotrace+ software 19 standard channels including right and left mastoid locations) with a sampling rate of 512 samples per second. Four separate flat type electrodes will be used to measure horizontal and vertical eye-movements.

Barrat impulsivity Scale -11

The Barrat Impulsivity Scale measures behavioural and personality construct of impulsivity across three factors: attentional, motor and nonplanning. It consists of 30 items scored on 4 point scale ranging from rarely/never to almost always/always.

Cued Go/No-Go task

The cued Go/No-Go task is a continuous performance test, measuring impulse control by the ability to inhibit prepotent responses.

DAQ

The desire for alcohol questionnaire (DAQ) is a self-report questionnaire assessing the desire to drink alcohol at the moment of assessment. It consists of four factors: intention to drink, desire to consume alcohol, anticipation of positive outcome from drinking, anticipation of relief of negative effect from withdrawal. A short-form of the questionnaire will be used, consisting of 14 items.

Secondary outcome

Actual drug-use

Number of urine samples collected will be counted, as will be positive (meaning drug-use in the period of time since last drug test) and negative (meaning no drug-use since last testing) outcome scores. Corresponding with clinical policy, refusal to undergo urine-analysis will be scored as a positive result.

Covariates (demographic characteristics, psychopathology, time in forensic treatment, actual drug use during the past 24 months, medication, clinical-risk assessment score, routine outcome measurements) will be collected through file information.

Study description

Background summary

Impulsivity and substance abuse disorder are strongly interconnected, with persons scoring high on impulsivity being more vulnerable for developing substance abuse and facing more challenges for successful treatment. Studies have shown high comorbidity rates between disorders characterized by behavioral disinhibition, such as attention deficit hyperactivity (ADHD) and/or conduct disorder (Iacono et al., 1999; Flory et al., 2003) and early-onset substance abuse problems.

Studies have shown that changes in EEG-frequencies such as theta, SMR and beta after neurofeedback treatment can affect motor control and cortical inhibition function (Sokhadze et al, 2011), and that short-term effects of neurofeedback-treatment can be comparable to the effects of medication in the treatment of symptoms such as inattention, hyperactivity and impulsivity (Fuchs et al., 2003). To date, however, there is no conclusive evidence about an impulsivity-based neurofeedback protocol and its effectiveness not only on impulsivity, but also on substance abuse related behaviour, such as level of craving and actual substance abuse.
This study aims to determine if neurofeedback-therapy can also reduce substance abuse related behavior by modulating levels of impulsivity in participants with substance abuse disorders and co-morbid Axis I and/or II diagnoses.

Study objective

1) Patients with substance abuse problems differ in levels of impulsivity, craving and resting-state EEG as compared to healthy controls.

2) A theta/SMR- based neurofeedback intervention can reduce symptoms of drug-seeking behaviour by modulating levels of impulsivity.

Study design

TO: Baseline measurements, where patients complete resting-state EEG, BIS-11, DAQ, cued Go/No-Go task.

T1: Outcome measurements - resting-state EEG, BIS-11, DQ, Cued Go/No-Go task.

Intervention

Participants in the intervention + TAU condition will receive 20 neurofeedback sessions, each lasting for approximately 40 minutes, in which EEG activity is measured across delta (0,5-3,5 hz), theta (3,5-7,5 hz), alpha (7,5-12 hz), low beta (12-20 hz), Sensorimotor rhythm (SMR,

12-15 hz), high beta (18-30 Hz) and gamma (>30 hz) frequency bands. To reduce inattention and impulsivity, a conventional neurofeedback protocol consists of enhancement of suppressing theta activity and enhancing low beta activity. Aim of the neurofeedback-sessions is to reduce slow waves (specifically theta) and increase SMR. The reinforced frequency band will be SMR (12-15 hz), the suppressed frequency band will be theta (3,5-7,5 hz). Other EEG alterations, such as excess delta (0,5-3,5 hz), and high beta (18-30 hz) will also be suppressed if participants present with them. A maximum of three frequency bands will be trained during each session.
Aim is to normalize qEEG alterations before starting SMR reinforcement. No other frequency band than SMR will be reinforced. Neurofeedback training will be done at electrode position Cz with mastoid reference. Each patient will undergo approximately two sessions a week. This session will last for 20 minutes.
No common serious side effects or risks are currently known to occur with this number of neurofeedback sessions.

The intervention will be compared at T0 and T1 to patients only receiving Treatment as usual.

Contacts

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Eligibility criteria

Inclusion criteria

1) Under inpatient forensic custody

2) Age 18 or older

2) Official DSM-IV-TR AS-I diagnosis of substance abuse disorder or substance dependency

3) Ability to give informed consent

4) Able to understand, speak, read and write the Dutch language sufficiently

5) Able and willing to comply to research requirements, such as attending appointments, being able to sit relatively still for 40 minutes.

Exclusion criteria

1) Acute psychosis or other severe, current psychiatric symptoms such as extreme manic, suicidal and/or aggressive symptoms

2) Acquired/congenital brain impairments, such as epilepsy

3) Visual and/or auditory impairments where participants are unable to follow neurofeedback-training

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2015
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-07-2015
Application type:	First submission

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
NTR-new	NL5279
NTR-old	NTR5386
CCMO	NL-46390.008.13

Study results