Pilot study into the effectiveness of neurofeedback as a treatment for major depressive disorder

Published: 25-03-2009
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The main objective of this pilot-study is to examine the effectiveness of NF in the treatment of major depression.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric disorders
Study type	Interventional

Summary

ID

NL-OMON33576

Source
ToetsingOnline

Brief title
Neurofeedback in depression

Condition

- Psychiatric disorders

Synonym
depression, major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: depression, effectiveness, neurofeedback, treatment

Outcome measures

Primary outcome

- Quick Inventory of Depressive Symptoms (QIDS)

- Hamilton Depression Rating Scale (HDRS)

- decrease of alpha-asymmetry

Secondary outcome

- Positive and Negative Affect Schedule (PANAS)

- Temporal Experience of Pleasure Scale (TEPS)

- Heartrate variability

Study description

Background summary

Major depressive disorder is a high-prevalent psychiatric disorder. Despite current available treatments, primarily pharmacotherapy and psychotherapy, partial remission and treatment resistance are common. Moreover, pharmacotherapy is associated with a number of undesirable side-effects. Apparently, there is quite some room for improvement. Neurofeedback (NF) for the treatment of depression has received increased attention in recent years. Within an operant paradigm, patients are connected to an EEG device that helps them, after analysis of brain-activity, to change brainactivity in certain areas. Feedback is given with a visual stimulus based on real-time analysis of the EEG.
Although there are widespread claims about its effectiveness, there is no scientific evidence that support these claims. No studies into the effectiveness have been carried out. There is some evidence from fundamental research into the neurophysiology of depression that NF may be helpfull indeed. Additionally, heart-rate variability (HV) appears to decreased in depression. In this study, an ECG will be made prior and after NF treatment to investigate whether NF is associated with increase in HV.

Study objective

The main objective of this pilot-study is to examine the effectiveness of NF in the treatment of major depression.

Study design

The current study is a open pilot-study in 10 depressed (according to the criteria of DSM-IV) patients.

Intervention

Participants will be treated with a maximum of 30 NF sessions in a frequency of 3 sessions each week. The maximum study duration in each participant will be 10 weeks. NF will be done on the basis of an alpha-asymmetry protocol. In this protocol, participants will learn through operant conditioning to decrease alpha-activity in left prefrontal regions and to increase alpha-activity in right prefrontal regions.

Study burden and risks

Neurofeedback sessions and filling-out self-report instruments do not constitute a burden or risk for the participants.

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

major depressive episode

Exclusion criteria

- history of brain trauma
- current use of antipsychotics, moodstabilisers, or benzodiazepines. current use of antidepressants is allowed if type and dosage are not changed during the study
- chronic depression (>2 years)
- dysthymia
- bipolar disorder
- lefthandedness
- severe depression or suicidality (HDRS >25)
- pregnancy
- other comorbid axis 1 disorders other than anxiety disorders or a personality disorder

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2009
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	25-03-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26159
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL25291.068.08
OMON	NL-OMON26159