Pilot-study into the effectiveness of neurofeedback in the treatment of major depressive disorder (MDD).

No registrations found.

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

Summary

ID

NL-OMON26159

Source
Nationaal Trial Register

Brief title
N/A

Health condition

major depressive disorder, depression

Sponsors and support

Primary sponsor: University Maastricht (UM), Department of Psychiatry and Neuropsychology
Source(s) of monetary or material Support: University Maastricht (UM), Department of Psychiatry and Neuropsychology

Intervention

Outcome measures

Primary outcome

1. Hamilton depression rating scale (17-item);

2. Baseline frontal alpha-activity in resting EEG.

Secondary outcome

Quick Inventory Depression Scale- SelfRating (16 items).

Study description

Background summary

It is claimed that neurofeedback (NF) is efficacious in the treatment of MDD. So far, no studies have systematically examined such claims. However, basic neurophysiological studies appear to support the premise of NF that depression is associated with frontal alpha-asymmetry in the resting EEG. Reduction of this FA is thought to be related to a decrease in depressive symptomatology. The aim of this pilot-study is to investigate the effectiveness of NF (delivered as a frontal asymmetry protocol) in MDD by (1) decreasing FA, and (2) reducing severity of depressive symptomatology.
In case of positive results in this pilot-study a larger scale RCT will be conducted.

Study objective

Neurofeedback is effective in the treatment of major depressive disorder.

Study design

1. Premeasure; diagnosis and assessment of clinical variables (like severity of MDD);

2. Measurement of MDD severity before every NF session;

3. Assessment of clinical variables (like severity of MDD) upon completion of the intervention.

1. Premeasure: 6 days ESM;

2. Postmeasure: after 8 weeks of mindfulness training/time control: 6 days ESM;

3. Follow-ups are planned, but were not yet submitted to ethical committee;

4. Follow-up at 6 months;

5. Follow-up at 12 months.

Intervention

Neurofeedback will be administered based by means of frontal alpha-asymmetry (FA) feedback. Baseline resting-EEG signal will be analyzed and individual thresholds will be used to provide real-time visual feedback in order to diminish FA. A maximum of 30 NF sessions will be delivered with a frequency of 3 sessions each week.

Contacts

Public
Department of Psychiatry
University Hospital Maastricht
P.O. Box 5800
F.P.M.L. Peeters
Maastricht 6202 AZ
The Netherlands
043-3874130
Scientific
Department of Psychiatry
University Hospital Maastricht
P.O. Box 5800
F.P.M.L. Peeters
Maastricht 6202 AZ
The Netherlands
043-3874130

Eligibility criteria

Inclusion criteria

1. MMD as a primary axis-1 diagnosis according to criteria of the DSM-IV-TR;

2. Informed consent.

Exclusion criteria

1. History of braintrauma (commotio or contusio cerebri);

2. Current use of antipsychotics, moodstabilizers, benzodiazepines. the use of antidepressants is permitted if type and dosage are not changed during participation in the

study;

3. Chronic MDD (>2 years duration of current episode);

4. Dysthymia;

5. Bipolar disorder;

6. Lefthandedness;

7. Severe (HDRS-17 > 25) episode of MDD which indicates prompt effective treatment;

8. Pregnancy;

9. Other psychiatric disorders other than co-morbid anxiety and personality disorders.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2009
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-01-2009

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33576
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1551
NTR-old	NTR1629
CCMO	NL25291.068.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON33576

Study results

Summary results
N/A