A randomised controlled trial of fMRI-neurofeedback in depression

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Primary Objective: To determine whether NFE + standard care is superior to standard care alone in the treatment of depression. Secondary Objective(s): To assess correlations between NFE success and brain activation / clinical changes; to assess...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON54250

Source
ToetsingOnline

Brief title
FMRI-neurofeedback in depression

Condition

- Mood disorders and disturbances NEC

Synonym
Affective Disorder, Depression

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Biofeedback, Depression, Magnetic Resonance Imaging, Neurofeedback

Outcome measures

Primary outcome

IDS (Inventory of Depressive Symptomatology) scores at post-intervention

between groups

Secondary outcome

1. Scores at post-intervention between groups for:

BDI (Beck Depression Inventory)

HADS (Hospital Anxiety and Depression Scale)

SES (Self Efficacy Scale)

QoL (Quality Of Life scale)

EQ-5D-5L (EuroQol research foundation questionnaire)

PsyMate depression questions

2. Scores after each neurofeedback session in

Profile of Mood States (POMS)

3. Neurofeedback performance

4. Changes in brain structure / activation over time

5. Correlations between neurofeedback performance and the other measures at

baseline, during the training and post intervention

Study description

Background summary

Neurofeedback (NF) enables patients to develop personal strategies that are most effective in self-regulating brain areas and networks associated with mental imagery through the feed-back of signals which reflect their own specific neural activation patterns. Previous studies suggest that participants can learn to control activity of brain areas involved in emotion processing within one or a small number of sessions of NF using real-time functional magnetic resonance imaging (rt-fMRI) signals. Because approximately a third of patients with depression do not respond satisfactorily to currently available (pharmacological or psychological) treatments it will be important to explore the use of this technique as a potential new add-on treatment for depression, which is one of the most common mental disorders. The PI*s group has recently completed a randomised controlled trial comparing an fMRI-neurofeedback (fMRI-NF) intervention targeting emotion networks with a control intervention targeting an area involved in the processing of scenes and places (both on top of standard medication). Although clinical benefits were considerable (over 40% improvement on a clinical rating scale), they did not differ between the groups, leaving open the possibility that patients would also have improved to the same degree with just their standard care (Mehler et al., 2018). The next step in the evaluation of this new technique will thus be to evaluate the fMRI-NF protocol targeting emotion networks (NFE) (plus standard care) against standard care alone. We hypothesise that training to gain control over the affective system and reinforcing neural correlates of positive emotions will elevate mood and diminish depressive symptoms that would otherwise remain with the current standard care.

Study objective

Primary Objective: To determine whether NFE + standard care is superior to standard care alone in the treatment of depression.
Secondary Objective(s): To assess correlations between NFE success and brain activation / clinical changes; to assess changes in brain structure and activation over the course of the NFE training; to assess NFE effects on other clinical domains; to assess long-term (6-month follow-up) effects of NFE; to find predictors of NFE success.

Study design

This is a single-blind interventional study, a randomised controlled clinical

trial of NFE + standard care vs. standard care.

NFE will be delivered in 5 sessions. After contact has been made through one of the collaborating clinical teams, a suitably qualified member of the study team will provide information about the study. One week after this patients will give consent and the screening assessment will be conducted to determine inclusion and exclusion criteria. Patients will then be invited to attend the baseline assessment after appr. one week and randomized. This also provides some delay for them to be able to re-consider their agreement and withdraw their consent before the actual start of the intervention if desired. Participants will additionally perform valence ratings of positive images used for localization of neurofeedback regions at the end of this session. After the baseline assessment, participants will undergo an experience sampling procedure for one week. For the NFE group this will be followed by four further visits for fMRI-NF sessions (for the NFE group) in appr. weekly intervals, and a fifth fMRI-NF session after a further month. Participants will train the self-regulation strategies used during the neurofeedback also at home. After appr. two months participants will undergo the experience sampling procedure again for one week before the post-study visit. The intervention will thus be concluded after appr. 10 weeks. A further follow-up visit (6 months after baseline assessment) will conclude the trial. The control group will only attend the screening, baseline, post-study and follow-up assessments. Before the start of the full trial we will pilot the assessment and scanning procedure in up to ten patients. This will only entail the five neurofeedback sessions and the baseline and follow-up assessment. This phase will allow us to adjust localizer and feedback parameters for optimal feasibility.

Intervention

Patients of the neurofeedback group take part in five neurofeedback sessions (four weekly sessions and one session four weeks after the fourth session). The fMRI-NF sessions will include anatomical scans, an fMRI localizer (visual presentation of standardized positive and neutral images to map emotion areas) and neurofeedback runs during which participants see a thermometer on a screen and are instructed to upregulate activation in brain areas that were identified based on their response to the positive images in the localizer procedure. Success of this upregulation is signaled by the level of the thermometer. Patients will receive some guidance as to potential mental strategies (e.g. remembering the positive pictures just seen) but no firm instructions. The principle of neurofeedback training is that patients optimize the strategies for self-regulation themselves. Patients will be asked to practice the successful up-regulation strategies at least twice per week for 10 minutes each and keep a diary about this.

Study burden and risks

Both groups will undergo an initial screening of appr. 1.5 hours duration, three clinical/psychometric assessments of appr. 1.5 hours duration (baseline, end of intervention (2 months from baseline), follow-up (6 months from baseline) and two weeks of experience sampling (one week following the baseline measurement and one week preceding the end of intervention measurement) consisting of ten brief daily questionnaires (daily load about 10m for six days per week) with a total duration of appr. 1hour per week. Participants will additionally rate positive images during the baseline measurement (0.5h). Participants of the neurofeedback group will undergo 5x2hour scanning sessions including psychological assessments (debriefing and mood scales). Patients of the neurofeedback group will also be asked to practice the successful up-regulation strategies at least twice per week for 10 minutes each and keep a diary about this (for the eight intervention weeks about 1.5h in total). The overall time commitment (excluding travel) will thus be appr. 20 hours for the intervention group and 8.5 hours for the standard care group. Patients will be compensated for their time (160¤ neurofeedback group, 110¤ control group) and travel costs. Expected benefits are clinical improvement over and above standard care in the intervention group. There are no known safety issues arising from fMRI-neurofeedback over and above general MRI safety requirements (for which strict guidelines implemented at Scannexus will be followed). The risk of adverse effects of the fMRI-neurofeedback procedure on patients* wellbeing is minimal and will be monitored through debriefing after each session.

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

1. Diagnosis of a depressive disorder (ICD-10: F32 or F33)
2. Has been on stable antidepressant medication (single or combination treat-ment) for at least 4 weeks
3. Currently depression (QIDS >= 17)
4. If required to meet recruitment targets the minimum entry score will be reduced QIDS >= 13 (i.e. still corresponding to a moderate level of depression)

Exclusion criteria

1. Exclusion criteria for MRI (e.g. cardiac pacemaker, certain metallic implants)
2. History of psychotic disorder bipolar disorder, or psychotic depression
3. Current use of illegal drugs (any in the last four weeks)
4. Current excessive alcohol consumption that interferes with daily functioning
5. History of neurological disease that could influence the fMRI signal and/or the ana-tomical alignment (e.g. territorial stroke, multiple sclerosis, brain tumour)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-04-2021
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	06-07-2020
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

No registrations found.

In other registers

Register	ID
CCMO	NL72785.068.20