Idiographic study of Neurofeedback to Ameliorate Mood in the Elderly (i-NAME); A pilot study with six patients.

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The primary objective of the present pilot study is: 1. To evaluate the temporal dynamics between neurofeedback parameters and depressive symptoms in older persons suffering from clinically relevant depressive symptoms. The secondary objectives are:...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Mood disorders and disturbances NEC
Study type	Observational non invasive

Summary

ID

NL-OMON43268

Source
ToetsingOnline

Brief title
i-NAME

Condition

- Mood disorders and disturbances NEC

Synonym
depression, major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Aged, Depression, Idiographic study, Neurofeedback training

Outcome measures

Primary outcome

Variance in depressive symptoms explained by changes in NF induced frontal alpha lateralization within individuals.

Secondary outcome

- Feasibility and patient burden of both NF training and data collection from a patient perspective

- Compliance to NF training and study procedures

- Psychopathology at baseline, and after 4, 8 and 12 weeks.

Study description

Background summary

EEG Neurofeedback training is an innovative and promising intervention for the treatment of psychiatric disorders associated with dysfunctional brain activity. EEG Neurofeedback training (NF) is able to change brain perfusion and metabolism, and more specific cortical excitability. Most evidence is available in the treatment of Attention Deficit Hyperactivity Disorder in adolescence, in which NF appeared a feasible and cost-effective treatment. Depressed patients show relative hypoactivation in the left prefrontal area, which differs from that found in normal people who show relative hyperactivation in the left prefrontal area. Neurofeedback training is hypothesised as a promising treatment for alleviating depressive symptoms by modulating this disbalance in frontal alpha activity. Some case studies as well as a randomised controlled pilot study showed that a relative increase in right frontal alfa-activity by an asymmetric neurofeedback training diminishes depressive symptoms. Whether change in (balance of right-left) prefrontal cortical activity underlies this improvement has to proven yet. In other words, it has to be proven whether a change in frontal alpha-symmetry precedes or follows an improvement of depressive symptoms.

Application of neurofeedback training requires frequent training sessions guided by clinicians. Consequently, the intervention is expensive limiting accessibility in routine clinical care. This has stimulated the development of methods enabling patients to train themselves in their natural environment (at home) at relatively low costs. This is especially relevant for older and less mobile patients. Recently, we have developed a neurofeedback device giving feedback by a tablet app enabling training at home. This device and training procedures were tested and considered feasible by non-depressed persons. Further testing of feasibility among depressed older persons, however, is needed before application in a large-scale randomised controlled trial.

Study objective

The primary objective of the present pilot study is:
1. To evaluate the temporal dynamics between neurofeedback parameters and depressive symptoms in older persons suffering from clinically relevant depressive symptoms.

The secondary objectives are:
2. To test the feasibility of EEG neurofeedback training in older persons suffering from clinically relevant depressive symptoms with the aid of a tablet application,
3. To evaluate the feasibility of a test battery that can be applied in larger, randomised controlled trials in case this pilot study is deemed successful.

Study design

We will use an idiographic study design, which focuses on individual patients, with multiple repeated measures. In total, 6 participants aged >=60 years with clinically relevant depressive symptoms will be studied during daily neurofeedback exercises in their home environment for 56 consecutive days. Before and after the daily neurofeedback exercises patients will fill in a diary, which consists of 23 visual analogues scales regarding mood symptoms.

Previous studies have shown that depressed older persons are capable of neurofeedback training as well as administration of a questionnaire to assess mood symptoms on a daily basis.

Using time-series analysis the temporal relationship between neurofeedback-induced changes in alpha-lateralisation and depressive symptoms will be evaluated on an individual patient level.

Study burden and risks

There are no risks involved in participating in the study. Previous studies on neurofeedback training in depressie did not reveal any side-effects.

Nonetheless, neurofeedback training in other psychiatric disorder do report headache and tiredness.

The burden of participating in the study consists of: 1) baseline assessments (filling out questionnaires), 2) undergo the 56-day study-period during which participants fill out the daily visual analogue scales (23 items) and undergo a NF session on a daily basis, 3) fill out a psychopathology battery of questionnaires for four times (at baseline, after 4, 8 and 12 weeks), 4) hand in devices and fill out questionnaire to assess feasibility and burden of NF training and study procedures.

Benefits for the participants may include an improvement in depressive symptoms due to the NF training.

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 60 years or over.
- Suffering from clinically relevant depressive symptoms defined as a score of 16 or more on the Center for Epidemiological Studies Depression Scale (CES-D) (Radloff, 1977; Eaton et al, 2004).
- Having met the criteria of Diagnostic and Statistical Manual of Mental Disorders (DSM-5) for a major depressive disorder (MDD) within the past 12 months (but no current MDD) as established with the Mini International Neuropsychiatric Interview (version 5.0).
- Right handedness.
- Giving informed consent after oral and written information about the study

Exclusion criteria

- Insufficient command of the Dutch language.
- Not capable of daily neurofeedback training.
- Major psychiatric comorbidity other than an affective disorder (encompassing mood-, anxiety or somatoform disorders).
- An established (or suspected) diagnosis of dementia or a neurodegenerative disorder.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	6
Type:	Anticipated

Ethics review

Approved WMO Date:	26-05-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL57402.042.16