Effects of a Neurofeedback Treatment on Psychological, Cognitive and Physiological (EEG) outcomes in patients suffering from cognitive decline

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON39679

Source
ToetsingOnline

Brief title
Neurofeedback on patients suffering from cognitive decline

Condition

- Dementia and amnestic conditions

Synonym
Cognitive decline, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: Geen

Intervention

Keyword: Cognition, dementia, EEG, Neurofeedback

Outcome measures

Primary outcome

The primaire primary study parameters in this study will be the psychological

(depression, behaviour), fysiological (EEG) and cognitive (memory, attention)

variables. Further, we will measur changes in Quality of Live.

Secondary outcome

nvt

Study description

Background summary

The number of people with dementia and cognitive decline will grow in the coming years. As a consequence, the demand for care and the costs of care will increase.
The existing treatments for dementia are few and sadly not very effective. Recently a new form of treatment has been developed that may be a good alternative. Neurofeedback, a treatment method that works through operant conditioning of the EEG has been proven to enhance attention and memory in healthy subject and subjects diagnosed with AD(H)D. The goal of this research is to find out if neurofeedback can improve functioning in people suffering from cognitive decline.
Recently, changes in EEG in cognitive decline have been described. This gives a possibility for neurofeedback to change these patterns.

Study objective

So far, only a few case-studies have been tried using neurofeedback in the treatment of dementia / cognitive decline. These indicate that there are behavioural changes and emotional changes next to cognitive changes. This will be the focus of this research; we hope that there will changes in the EEG

(physiological changes), psychological changes and cognitive changes.

Study design

The design of the study is a RCT with a cross-over design. The control group recieves treatment as usual, the experimental group treatment as usual plus neurofeedback. There will also be a healthy control group.

Intervention

The intervention group will receive 30 session of neurofeedback, twice a week. The controlgroup recieves treatment as usual. After 30 sessions, the groups will switch. The healthy controls do not have a "waitinglist" condition.

Study burden and risks

Before and after the treatment sessions participants will undergo an EEG-examination. This, together with the fact that participants will have to come to the hospital twice a week, will be the greatest burden on the participants. Further, the participants will have to complete a few questionnaires and a short neuropsychological screening, which is mostly part of the standard procedure of the *geheugen onderzoek centrum*.

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

Diagnosis: Cognitve decline as diagnosed by the Catharina hospitals memory clinic .
Healthy controls

Exclusion criteria

Neurological history (epilepsy, strike, braintumors)
impaired vision or hearing (glasses or hearingaid is not sufficient for vision or hearing)
Insufficient knowledge of the dutch language
The patients EEG and qEEG do not meet the criteria as discribed in the literature

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	27-01-2010
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO Date:	13-02-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-02-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL25685.060.08