ADHD and EEG-Neurofeedback. A randomised placebo-controlled treatment study

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1) To investigate the efficacy of EEG-neurofeedback in reducing behavioral symptoms of ADHD.2) To investigate whether EEG-neurofeedback is able to improve neurocognitive functioning. 3) To investigate whether EEG-neurofeedback is able to improve...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON32034

Source
ToetsingOnline

Brief title
ADHD & EEG-Neurofeedback

Condition

- Personality disorders and disturbances in behaviour

Synonym
Attention-deficit / Hyperactivity Disorder (ADHD)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Smartmix fonds

Intervention

Keyword: ADHD, Efficacy, Neurofeedback, Treatment

Outcome measures

Primary outcome

ADHD-DSM-IV rating scale, rated by the investigator

Secondary outcome

scores on all neuropsychological tasks

absolute en relative power of 4 frequenties EEG bands

fluctuations in de BOLD signals on fMRI

measures on the diffusion Tensor Imaging (DTI)

Study description

Background summary

EEG-neurofeedback has been shown to offer therapeutic benefits to patients with ADHD in several relatively small and mostly uncontrolled studies. It is unknown how EEG-neurofeedback affects brain functioning and exerts therapeutic effects in ADHD. This controlled treatment is designed to examine the efficacy and safety of EEG-neurofeedback in a scientific rigorously way and to study the underlying neurobiological mechanisms of EEG-neurofeedback.

Study objective

1) To investigate the efficacy of EEG-neurofeedback in reducing behavioral symptoms of ADHD.
2) To investigate whether EEG-neurofeedback is able to improve neurocognitive functioning.
3) To investigate whether EEG-neurofeedback is able to improve neural functioning/connectivity.

Study design

Double-blind randomized placebo-controlled treatment study

Intervention

60 subjects with ADHD receive 30 sessions EEG-neurofeedback, 60 subjects with ADHD receive placebo EEG-neurofeedback.

Study burden and risks

Risks or side-effects are not expected. The burden for the ADHD subjects in the two treatment modalities exists of the pre- and post-treatment assessment (different duration, depending on fMRI allocation) and 30 visits of approximately 45 minutes for the EEG-neurofeedback. The benefit exists of the a priori change of positive effect of the EEG-neurofeedback on ADHD symptoms.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Diagnosis ADHD (classified by the DSM-IV TR)
Age between 8 and 15
A full scale IQ ³ 80
Medication- naïve, or using psychostimulants/atomoxetine but still with room for improvement

Exclusion criteria

Currently intensive (i.e. weekly) individual or group psychotherapy.
Use of medication other than psychopharmaca
Diagnosis of one or more of the following comorbid psychiatric disorders:
Major depression or dysthymie
Anxiety disorder
Bipolar disorder
Psychotic disorder
Chronical motor tic disorder or Gilles de la Tourette
Conduct disorder
Autism spectrum disorders
Eating disorders
Cardiovascular disease currently/in the past
Neurological disorders (e.g. epilepsy) currently or in the past
Participation in another clinical trial simultaneously
Neurofeedback training in the past
Metal parts in body

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-08-2009
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	14-07-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL21590.091.08

Study results

Date completed:	01-09-2012
Actual enrolment:	41