Effectivity of Neurofeedback in youth with AD(H)D-problems and comorbid disorders: a randomized controlled trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON33860

Source
ToetsingOnline

Brief title
RCT neurofeedback

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD, Attention Deficit Hyperactivity Disorder

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Eindhoven (Eindhoven)
Source(s) of monetary or material Support: Zon MW

Intervention

Keyword: ADHD, Adolescent Behavior, Biofeedback, Electroencephalography

Outcome measures

Primary outcome

The effectivity of neurofeedback is investigated with different study parameters. We expect that the brain after neurofeedback will be better capable to proces information than before the neurofeedback; this will be indicated using Event Related Potentials which are determined during the QEEG. Also we expect that the sustained and selective attention and concentration will increase and the executive functions improve. To indicates these changes (neuro)psychological tests will be assessed. Whenever the fundamental problems of AD(H)D-problems are effectively treated we expect that the related behavior problems decrease. Therefore behavioral changes will be investigated using behavioral questionnaires and an interview.

Secondary outcome

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Study description

Background summary

Youngsters in (forensic) mental health care suffer from complex and multiple behavioral problems which are, to a certain extent, untreatable. These complex behavioral problems are most often related to a dysfunctional regulation of brain activity (John, 1988). Neurofeedback is a training method to (partially) correct the regulation of the brain activity by feedback. The goal of this training is to learn youngsters to regulate their brain activity and thereby indirectly influence their behavior. Earlier studies demonstrate that neurofeedback causes sustained and structural changes in brain activity

(Strawson & Gruzelier, 2002). Furthermore, these changes cause a longstanding improvement of the behavior (Lubar, 1997).

Study objective

The objective of the study is to investigate, using a randomized controlled trial, whether a neurofeedback is a effective intervention for youngsters with AD(H)D and comorbid disorders. The objective of neurofeedback is to treat the fundamental problems related to AD(H)D-problems.

Study design

In a randomized controlled trial the effectivity of neurofeedback will be investigated. The RCT uses an experimental group (with treatment as usaul [TAU] and 40 session of neurofeedback) and a control group (TAU) with youngsters with AD(H)D-problems and comorbid disorders. The clients are enrolled in the study after a positive screening for AD(H)D or a DSM IV diagnosis AD(H)D. Information about AD(H)D is assessed with a semi-structured interview, questionnaires (in interview format) and neuropsychological tests. All these measurements will be assessed on four different occasions: (1) During the intake; (2) directly after the neurofeedbacktraining; (3) half year after the completion of the neurofeedbacktraining; (4) and a year after the end of the neurofeedbacktraining.

Intervention

The neurofeedbacktraining will be conducted in 40 sessions, 30 minutes each. There are three sessions per week, which are divided equally across the week. The total duration of the neurofeedbacktraining is 14 weeks. The procedure follows the paradigm described by Lubar et al. (1995). During the neurofeedbacktraining the EEG is recorded with 3 electrodes. The EEG will be recorded on C3 or C4 (10-20 system) with a reference to both ears (mastoid earth sensor, 256 Hz).
During the training several EEG frequencies are trained: in clients with mostly hyperactivity and impulsive symptoms the sensory motor rhythms are trained, in clients with mostly attention deficit symptoms the beta1 frequencies are trained. In clients with mixed symptoms the training of sensory motor rhythms and beta1 frequencies are alternated trained. Furthermore during the last and the first session of the neurofeedbacktraining a QEEG-assessment is conducted, based on the first QEEG the protocol of the neurofeedbacktraining is determined.

Study burden and risks

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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* A positive screen on the Screeningslist ADHD or DSM IV diagnosis ADHD
* IQ > 80

Exclusion criteria

* IQ < 80
* suffer or have suffered from a medical condition that causes attention problem or hyperactivity (for example: anaemia, organic brain damage, low blodd sugar levels)

* instable EEG pattern, determined with QEEG assessment

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2009
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	08-05-2009
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-12-2009
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Not approved Date:	09-07-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22925
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL24776.097.08
OMON	NL-OMON22925