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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22925

Source
Nationaal Trial Register

Brief title
RCT Neurofeedback

Health condition

Neurofeedback
ADHD
EEG

Sponsors and support

Primary sponsor: Zon MW
Source(s) of monetary or material Support: GGzE; Stichting Geïntegreerde Geestelijke Gezondheidszorg in Eindhoven en de Kempen

Intervention

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

N/A

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).
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.
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.
In the RCT male clients with AD(H)D-problems and comorbid disorders, like alcohol or drugs dependence and conduct disorder, that are treated by a youth (forensic) psychiatric (outpatient) clinic are included. The clients will be approached at admission in three different settings: (A) (outpatient) clinic for forensic youth psychiatry and orthopsychiatry (mental health settings and correctional institute for juvenile offenders), (B) (outpatient) clinic for

adolescent psychiatry, (C) outpatient clinic for children- and adolesent psychiatry. There will be 100 male clients between 12 and 24 years included in the experimental condition and 50 clients in the control condition (Total N = 150). The ethical background of the clients is not important because brain disturbance is culture free. Clients are excluded from the study when (1) they score negative on the screening for AD(H)D or have no DSM IV AD(H)D diagnosis ; (2) they have a WAIS or WISC IQ<80; (3) they have an instable EEG pattern; (4) suffer or have suffered from medical conditions which cause attention deficit or hyperactivity (e.g. anaemia, organic brain damage, low blood sugar levels).
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.
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.

Study objective

De volgende onderzoeksvragen staan centraal:

1. Is een neurofeedbacktraining in staat om de verstoorde hersenenfrequenties te veranderen bij
jongeren met AD(H)D en comorbide stoornissen?

2a. Heeft een neurofeedbacktraining effect op de volgehouden aandacht, verdeelde aandacht en
executieve functies van jongeren met AD(H)D en comorbide stoornissen?

2b. Is de ernst van de AD(H)D-klachten van invloed op het effect van de neurofeedbacktraining op de
volgehouden aandacht, verdeelde aandacht en executieve functies van jongeren met AD(H)D en

comorbide stoornissen?

3. Is de invloed van neurofeedback na een (half) jaar nog steeds aantoonbaar op de volgehouden
aandacht, verdeelde aandacht en executieve functies van jongeren met AD(H)D en comorbide
stoornissen?

Study design

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. A year after the end of the neurofeedbacktraining.

Intervention

Neurofeedback will be administered. Baseline resting-EEG signal will be analyzed and individual thresholds will be used to provide real-time visual feedback in order to diminish ADHD-problems. A maximum of 40 NF sessions will be delivered with a frequency of 3 or 2 sessions each week.

Contacts

Public
Ch. Nieuwenhuizen, van
Eindhoven
The Netherlands
Scientific
Ch. Nieuwenhuizen, van
Eindhoven
The Netherlands

Eligibility criteria

Inclusion criteria

* Male * Between 12 and 24 years old *A positive screen on the screeningslist ADHD of Kooij (clinical: more than six points on one of the scales or subclinical: four or more points on one of the scales) or a DSM IV diagnosis ADHD *Dutch as native language *Diagnosed with a comorbid disorder.

Exclusion criteria

*A total IQ-score < 80 points on the WAIS or WISC intelligence scales *An instable EEG-pattern (epilepsy) *Having a medical condition that account for attentional problems or hyperactivity (organic brain damage), presentation of a psychotic disorder or schizophrenia.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2008
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-04-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33860
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1660
NTR-old	NTR1759
CCMO	NL24776.097.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON33860

Study results

Summary results
N/A