

# Neurofeedback a possible effective intervention for youth with AD(H)D and comorbid severe behavioral problems.

Published: 29-01-2008

Last updated: 10-05-2024

The objective of the pilot study is to investigate whether a neurofeedbacktraining is a feasible intervention for youngsters with AD(H)D and severe behavioral problems. Besides the feasibility of the neurofeedbacktraining the clinical relevance of...

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

## Summary

### ID

NL-OMON31819

### Source

ToetsingOnline

### Brief title

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:** Ministerie van Justitie;WODC

## Intervention

**Keyword:** ADHD, Adolescent Behavior, Biofeedback, Electroencephalografie

## Outcome measures

### Primary outcome

The feasibility and the clinical relevance are investigated with different study parameters. For the feasibility the number of the followed neurofeedbacktraining are registered and the attitude towards the training. For the clinical relevance of the neurofeedbacktraining for youth with AD(H)D and severe behavioural problems a QEEG assessment is conducted before and after the neurofeedbacktraining. Secondly using neuropsychological test the dysfunctioning related to the ADHD symptoms are described on four measurement moments.

### 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

2 - Neurofeedback a possible effective intervention for youth with AD(H)D and comorb ... 5-05-2025

The objective of the pilot study is to investigate whether a neurofeedbacktraining is a feasible intervention for youngsters with AD(H)D and severe behavioral problems. Besides the feasibility of the neurofeedbacktraining the clinical relevance of the neurofeedbacktraining is important for continuation of the training in youth with AD(H)D and severe behavioral problems. Therefore thev clinical relevance of the neurofeedbacktraining is investigated using QEEG-assessment and neuropsychological tests.

## **Study design**

In the pilot study a neurofeedbacktraining will be investigated in (delinquent) youth with AD(H)D and severe behavioral problems who are hospitalized in a youth (forensic) psychiatric hospital. The clients are enrolled in the study after a positive screening for 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 6 electrodes. The EEG will be recorded simultaneous on C3 and 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

### Public

GGZ Eindhoven (Eindhoven)

Postbus 909  
5600 AX Eindhoven  
NL

### Scientific

GGZ Eindhoven (Eindhoven)

Postbus 909  
5600 AX Eindhoven  
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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 Screeninglist ADHD (Kooij, 2002)
- \* IQ>80

### Exclusion criteria

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

\* instable EEG pattern, determined with QEEG assessment

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-03-2008

Enrollment: 28

Type: Actual

## Ethics review

Approved WMO

Date: 29-01-2008

Application type: First submission

Review commission: METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Approved WMO

Date: 16-07-2008

Application type: Amendment

Review commission: METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

## 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**

<b>Register</b>	<b>ID</b>
CCMO	NL19599.097.07