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# Comparison of neurofeedback and computerised attention skills training in children with attention-deficit/hyperactivity disorder (ADHD)

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 31/03/2008 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 15/05/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 04/07/2011 | Mental and Behavioural Disorders | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
MO-726/2

# Study information

### Scientific Title
Neurofeedback in children with attention-deficit/hyperactivity disorder: clinical efficacy and neurophysiological mechanisms

### Acronym
Neurofeedback - ADHD

### Study objectives
1. Neurofeedback training is more effective than a computerised attention training in children with attention-deficit/hyperactivity disorder (ADHD)
2. Neurophysiological mechanisms of a successful neurofeedback training can be revealed (distinct patterns for different neurofeedback protocols)

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics approval received from the Ethics Committee of the University of Erlangen on the 29th April 2004 (ref: 3135).

### Study design
Randomised, controlled, multicentre clinical trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Attention-deficit/hyperactivity disorder (ADHD)

### Interventions

Experimental intervention: neurofeedback training (comprising so-called theta/beta training and training of slow cortical potentials)
Control intervention: computerised attention skill training

Children are randomly assigned to one of the two trainings. Both trainings consist of two blocks of 18 sessions (double sessions of about 50 minutes each, separated by a short break), two to three double sessions a week. There is an intermission of about two to three weeks between the two blocks. In the training, the children develop strategies for focusing their attention and are instructed on how to practice these strategies at home and in school.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Changes from baseline to end of training in ADHD symptoms (German ADHD rating scale[FBB-HKS]).

### Secondary outcome measures
Behavioural level (parent and teacher ratings):
1. Positive and negative attributes using the Strength and Difficulties Questionnaire (SDQ-D)
2. Oppositional behaviour and delinquent and physical agression (FBB-SSSV)
3. Behaviour problems of the child in specific home situations (HSQ-D); including homework (HPC-D)

Neurophysiological level:
4. Brain electrical activity measures (electroencephalogram [EEG], event-related potentials) at rest and during computerised attention tasks

All measures are assessed at baseline, between the two training blocks and at the end of training. Behavioural measures will additionally be assessed at the six-month follow-up.

### Overall study start date
01/05/2005

### Completion date
30/09/2008

## Eligibility

### Key inclusion criteria
1. Aged 8 - 12 years
2. Gender: both
3. Attention-deficit/hyperactivity disorder (ADHD) (Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition [DSM IV] criteria: combined type or predominantly inattentive)
4. Children with the following associated disorders are allowed to participate:
4.1. Conduct disorders

4.2. Tic disorders
4.3. Emotional disorders
4.4. Dyslexia

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
8 Years

### Upper age limit
12 Years

### Sex
Both

### Target number of participants
120

### Key exclusion criteria
1. Comorbid disorders other than those mentioned in the inclusion criteria
2. Gross neurological or other organic disorders
3. Pharmacological treatment or other psychotherapies
4. Intelligence quotient (IQ) less than 80

### Date of first enrolment
01/05/2005

### Date of final enrolment
30/09/2008

## Locations

### Countries of recruitment
Germany

### Study participating centre
**University of Erlangen**
Erlangen
Germany
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## Sponsor information

### Organisation
University of Erlangen (Germany)

### Sponsor details
c/o Prof. Dr. Gunther Moll
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### Sponsor type
University/education

### Website
http://www.klinikum.uni-erlangen.de

### ROR
https://ror.org/00f7hpc57

## Funder(s)

### Funder type
Research organisation

### Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | main results | 01/07/2009 | | Yes | No |

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|---|---|---|---|---|
| Results article | results on EEG effects | 01/11/2009 | Yes | No |
| Results article | result | 01/05/2011 | Yes | No |