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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
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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

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