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Neurofeedback in children with attention deficit hyperactivity disorder (ADHD)

Submission date
20/01/2009

Recruitment status
No longer recruiting

Registration date
05/02/2009

Overall study status
Completed

Last Edited
18/04/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Attention-deficit/hyperactivity disorder (ADHD) is the most common behavioral disorder of childhood. Key symptoms include impaired attention, excessive motor activity, and impulsivity. At present, drugs like methylphenidate are the preferred treatment for children who have ADHD. Among alternative treatments, Neurofeedback is a non-invasive treatment for children with ADHD. Neurofeedback is a procedure that encourages the individual to exercise a certain amount of self-control over his/her 'brainwaves' as recorded by an electroencephalogram. The aim is that the children learn how to bring their neurophysiological profile closer to that of non-ADHD children, resulting in improvements in behaviour and cognition. This study will examine how well Neurofeedback works for children with ADHD in comparison to an unspecific peripheral biofeedback treatment (muscular relaxation).

Who can participate?
Children with a clinical diagnosis of ADHD and aged between 7 and 10 years old.

What does the study involve?
Children will be randomly allocated to either an average of 25 sessions of Neurofeedback or peripheral biofeedback training in 3 months. Each session will last about 60 minutes. After a six-month period, a follow-up examination will be conducted focusing on the long-term effects.

What are the possible benefits and risks of participating?
Until now, no serious side effects of Neurofeedback or peripheral biofeedback have been reported.

Where is the study run from?
Department of Child and Adolescent, Ruhr-Universität Bochum (Germany),

When is the study starting and how long is it expected to run for?
From April 2009 to April 2012.

Who is funding the study?
The project is funded by the Deutsche Forschungsgemeinschaft (DFG), Germany.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DFG HO2503 4/1

Study information

Scientific Title
Neurofeedback in children with attention deficit hyperactivity disorder (ADHD): a single-blind randomised controlled trial

Acronym
Feedback

Study objectives
Preliminary results indicate that neurofeedback showed specific effects on impulse control in attention deficit hyperactivity disorder (ADHD) children. Futhermore, significant improvement in behaviour, attention and intelligence quotient (IQ) was observed after neurofeedback. Despite these promising results, there is still a lack of evidence on whether the observed effects are caused specifically by this intervention and are not due to unspecific effects only. The primary objective is to investigate the effects of neurofeedback on core symptoms of ADHD.

On 14/07/2011 the overall trial end date was changed from 01/04/2011 to 01/04/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Department of Medicine, Johann Wolfgang Goethe University, 08/01/2009, ref: 297/08

Study design
Single-blind randomised controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Participants will be randomly allocated to the following two groups (1:1 randomisation ratio):

Intervention group:
Neurofeedback of slow cortical potentials in addition to treatment as usual (TAU). Treatment of subjects will be performed in four trial centres. Children will attend an average of 25 sessions of neurofeedback training in 3 months. Each session is expected to last approximately 60 minutes. This will include time needed for electrode montage as well as 4 x 10 minute feedback segments.

Control group:
Peripheral electromyographic (EMG) biofeedback in addition to TAU. Children assigned to the EMG group will attend an average of 25 sessions of peripheral EMG biofeedback (muscular relaxation at different regions of the body). Duration of sessions, surface of the feedback device, reinforcement and transfer exercises will be identical to the neurofeedback setting.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Change in ADHD Rating Scale at pre-test, treatment phase, post-test 1, post-test 2, follow-up.

Secondary outcome measures
The following will be assessed at pre-test, post-test 1, post-test 2, follow-up:
1. Clinical Global Impressions - Severity (CGI-S) Scale (at pre-test) and Clinical Global Impressions - Improvement (CGI-I) Scale (at post-test 1, post-test 2, follow-up)
2. Resumption of medication by choice of family during follow-up (yes/no)
3. Change in neuropsychological and neurophysiological parameters

Overall study start date
01/04/2009

Completion date
01/04/2012

Eligibility

Key inclusion criteria
Subjects meeting all of the following criteria will be considered for admission to the trial:
1. Both males and females, aged 7 to less than 10 years inclusive
2. Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) diagnosis of ADHD, combined type
3. Ability of subject to understand character and individual consequences of clinical trial
4. Written informed consent must be available before enrolment in the trial
5. For women with childbearing potential, adequate contraception

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
144

Key exclusion criteria
1. Below IQ 80 (Culture Fair Test [CFT])
2. Bipolar disorder, psychosis, serious obsessive compulsive disorder (OCD), chronic serious tics or Tourette syndrome
3. Pharmacotherapy for severe anxiety and mood disorders and psychosis
4. Major neurological or medical illness

5. Non-German speaking child and primary caretaker
6. No telephone
7. Suicidal
8. Pregnancy and lactation
9. Participation in other clinical trials and observation period of competing trials, respectively

Date of first enrolment
01/04/2009

Date of final enrolment
01/04/2012

Locations

Countries of recruitment
Germany

Study participating centre
LWL University Hospital Hamm of the Ruhr- Universität Bochum
Hamm
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59071

Sponsor information

Organisation
Ruhr-Universität Bochum (Germany)

Sponsor details
Department of Child and Adolescent
Psychiatry and Psychotherapy
Postbox 102148
Bochum
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44721

Sponsor type
Hospital/treatment centre

Website
http://www.ruhr-uni-bochum.de

ROR
https://ror.org/04tsk2644

Funder(s)

Funder type
Research council

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) (ref: GZ: HO 2503/4-1)

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?
Protocol article	protocol	13/08/2014		Yes	No
Results article	results	31/03/2017		Yes	No