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Neurofeedback with direct training of specific brain regions compared to other biofeedback training methods in patients with Attention Deficit Hyperactivity Disorder (ADHD)

Submission date
20/01/2010

Recruitment status
No longer recruiting

Registration date
02/02/2010

Overall study status
Completed

Last Edited
02/02/2010

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Renate Drechsler

Contact details
Neumuensterallee 9
Zurich
Switzerland
8032
renate.drechsler@kjpd.uzh.ch

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Specificity of tomographic neurofeedback training compared to other biofeedback training methods in patients with ADHD: A randomised controlled trial.

Study objectives
There is growing evidence that neurofeedback training is an effective treatment method for ADHD, but its specificity and underlying mechanisms still need to be explored.

In this study, we investigate specific and unspecific effects of three biofeedback training methods: 1. tomographic neurofeedback, 2. conventional neurofeedback and 3. Electromyogram (EMG) biofeedback.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Cantonal Ethical Committee of the Canton of Zurich, Subcommission on psychiatry, neurology, neurosurgery (Kantonale Ethikkommission des Kantons Zürich, Unterkommission für Psychiatrie, Neurologie, Neurochirurgie) approved on the 3rd of October 2008 (ref: E57/2005)

Study design
Single centre prospective controlled randomised parallel groups intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.kjpd.uzh.ch/research/focus/focus1/Studien-Neurofeedback.pdf

Health condition(s) or problem(s) studied
Attention Deficit Hyperactivity Disorder (ADHD)

Interventions
Interventions consist of three biofeedback-training methods, using the same training software and parallel training protocols:
1. Tomographic neurofeedback allows targeting the frontal brain regions which are most affected in ADHD (lateral and mesial), and train patients to modify their activation within these areas according to specific training protocols. To this end, current densities are computed using the standardized Low Resolution Brain Electromagnetic Tomography (sLORETA) algorithm and

fed back visually to the subjects in order to change the activation in the particular Regions of Interest (ROIs).
2. In conventional neurofeedback the signal is fed back from the surface of the scalp by one electrode.
3. In EMG-biofeedback, fine motor regulation is fed back.
Duration: 18 double training sessions, over a period of 10-12 weeks. The total follow up time will be 3 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Clinical ADHD scales (parent-, teacher-, self-report)
2. Neuropsychological tests (subtests from computerised test batteries Test for Attentional Performance [TAP], Child-TAP [Kinder-TAP; KITAP] and D2)
3. Quantitative Electroencephalography (qEEG) and Event-Related Potentials (ERPs)
Measured at baseline and 3-month follow-up.

Secondary outcome measures
Quantitative measures of learned control during the biofeedback training.
Measured at each training session.

Overall study start date
01/03/2009

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Diagnosis of ADHD
2. Children (age >8.5) and adults (age >18).

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
80

Key exclusion criteria

1. (Severe) psychiatric comorbidity
2. Neurological diseases
3. IQ<80

Date of first enrolment
01/03/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Switzerland

Study participating centre
Neumuensterallee 9
Zurich
Switzerland
8032

Sponsor information

Organisation
University of Zurich (Switzerland)

Sponsor details
Department of Child and Adolescent Psychiatry
Neumuensterallee 3-9
Zurich
Switzerland
8032

Sponsor type
University/education

Website
http://www.kjpd.unizh.ch/index.html

ROR
https://ror.org/02crff812

Funder(s)

Funder type
Government

Funder Name
European Union - EU Project (COST-B27 ENOC / C06.0071)

Funder Name
Department of Health of the Canton of Zurich (Switzerland)

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