ISRCTN12800253 https://doi.org/10.1186/ISRCTN12800253

Neurofeedback in children with attention deficit hyperactivity disorder (ADHD)

Submission date
12/03/2012

Recruitment status
No longer recruiting

Registration date
27/03/2012

Overall study status
Completed

Last Edited
01/03/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] 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 child psychiatric disorder. It is a group of behavioural symptoms that include inattentiveness, hyperactivity and impulsiveness. The most common treatment is medication, but this has side effects. This study aims to test a new treatment for ADHD called neurofeedback.

Who can participate?
Patients aged between 12 and 18 with ADHD.

What does the study involve?
Participants are randomly allocated to either the intervention group or the control group. Participants in the intervention group undergo neurofeedback, where they are taught to increase the activity of certain brain regions that we know are not functioning well in ADHD. Neurofeedback in these regions will be compared with neurofeedback in other brain regions. This is done in 4 visits over 2 weeks. The control group are asked to do the same but on a different brain region.

What are the possible benefits and risks of participating?
It is expected that patients will benefit from the neurofeedback training as it will improve their ADHD symptoms. There are no known side effects of neurofeedback.

Where is the study run from?
Institute of Psychiatry, King's College London (UK)

When is the study starting and how long is it expected to run for?
September 2012 to March 2015

Who is funding the study?
Action Medical Research (UK)

Who is the main contact?
Prof. Katya Rubia

Contact information

Type(s)
Scientific

Contact name
Prof Katya Rubia

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Neurofeedback using functional magnetic resonance imaging in patients with attention deficit hyperactivity disorder (ADHD)

Study objectives
The hypothesis is that ADHD children will be able to progressively upregulate right frontal cortex and caudate activations in 16 sessions of 10 minutes of fMRI-Neurofeedback and that this upregulation will be associated with an improvement in symptom severity of inattention, hyperactivity and impulsiveness as measured in ADHD behavioural rating scales

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design

Randomised controlled 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

Interventions
Neurofeedback using functional magnetic resonance imaging (FMRI-NF)

Patients will undergo Neurofeedback to learn to upregulatetheir own brain activation in 16 sessions of 5 minutes each. This will be done over 4 MRI sessions. Within each FMRI session there will be 4 sessions of 5 minutes each. This will be done over 4 visits over 2 weeks.

The control group will be asked the same but on a different brain region.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The ADHD Rating Scale (ADHD-RS)(Dupaul et al., 1998), measured before and after the treatment
2. Monotonic increase in inferior frontal lobe and caudate activation across the feedback sessions in the active group

Secondary outcome measures
1. Reduction in the ADHD Index of the Conners Parent Rating Scale
2. Reduction in the Childrens Global Assessment Scale (CGAS), a clinical rating scale used to document childrens overall functional capacity at home, school, and with peers
3. No side effects as measured on a side effects scale
IMprovement in a cognitive task battery we have developed for ADHD that measures key functions including inhibition, attention, timing and motivation

Overall study start date

01/09/2012

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. Between the age of 12 and 18 years
2. Score above clinical cut-off on the Schedule for Affective Disorders and Schizophrenia, ADHD module (K-SADS) (Kaufman, Birmaher, Brent, Rao, & Ryan, 1996)
3. Score above clinical cut-off on the Conners Parent and Teacher Rating Scales (CPRS/CTRS) (Conners, Sitarenios, Parker, & Epstein, 1998)
4. Score above cut-off on the ADHD Rating Scale (ADHD-RS) (Dupaul, Power, Anastopoulos, & Reid, 1998).
5. Patients will be either medication naïve or on their usual stable medication without change in regime throughout the study.
6. Comorbidity with other disorder will be allowed except the ones outlined below under exclusion criteria
7. IQ > 80

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Neurological disorder
2. Epilepsy
3. Drug and alcohol abuse/dependence (as assessed by K-SADS)
4. Comorbidity with schizophrenia, Bipolar disorder, learning disability, severe depression with current suicidal behaviour (as assessed on Kiddie-SADS)
5. IQ < 80

Date of first enrolment
01/09/2012

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Institute of Psychiatry
De Crespigny Park
London
England
United Kingdom
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Sponsor type
University/education

Website
http://www.kcl.ac.uk/iop

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research organisation

Funder Name
Action Medical Research (UK) ref: 1890

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	proof-of concept study results	01/06/2017		Yes	No