

Neurofeedback in children with attention deficit hyperactivity disorder (ADHD)

Submission date 12/03/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/03/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/03/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

ORCID ID

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Contact details

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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 upregulate their own brain activation in 16 sessions of 5 minutes each. This will be done over 4 fMRI 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

SE5 8AF

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