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Attention control training for infants at risk of ADHD

Submission date
19/06/2015

Recruitment status
No longer recruiting

Registration date
22/06/2015

Overall study status
Completed

Last Edited
22/12/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Attention deficit/hyperactivity disorder (ADHD) is a developmental condition that has a significant impact on a person's education, social development and communication. Medication is often used as a treatment but this has limited effects. Psychological approaches, although more acceptable to many, have not worked well, perhaps due to being administered too late in development. The best time to intervene is likely to be in infancy, before the disorder fully develops and when brains are more amenable to positive environmental effects. To test this idea we will undertake a study of a novel computer-based attention training treatment for infants identified as being at increased genetic risk for ADHD. The training approach uses state of the art technology to link attention allocation (as measured by infant gaze) to rewarding images and outcomes on the screen – thus reinforcing concentration and strengthening attention capacity (as previously shown in typically developing infants). We are interested to see whether such effects can also be seen in infants at risk for ADHD, whether there are knock-on effects on early manifestations of ADHD behaviours, and what the brain processes underpinning such effects might be. If the initial study is successful, we will plan a larger scale effectiveness RCT in the near future.

Who can participate?
Children under 14 months old identified as being at increased genetic risk of ADHD as they all have an immediate family member with a diagnosis of ADHD and/or hyperactive symptoms.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (training group) are given up to 9 weekly 'in home' sessions of the computer-based training over a 3 month period (one session a week). Those in group 2 (control) are given up to 9 weekly 'in home' sessions (over a 3 month period) of non-contingent videos. The aim is to run the sessions at the participants family home but they can be run in the clinic or in the lab based on the family's needs and wishes. Pre-training (10-14 months) and post-training assessments (14-18 months) are administered both at home and in the lab, at the Centre for Brain and Cognitive Development (CBCD). An intermediate home-based assessment is also carried out after the first five training sessions. In additional, longer-term follow-ups occur at 24 and 36 months through a linked study (MRC-STAARS).

What are the possible benefits and risks of participating?
Over the course of the study, participants will have the opportunity to learn about research in ADHD and interact directly with researchers in the field. In the long term, this study will benefit future families of children with ADHD. There are no notable risks associated with taking part in this study.

Where is the study run from?
Centre for Brain and Cognitive Development (London), University of Southampton, King's College London, South London and Maudsley NHS Foundation Trust and the Solent NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2015 to September 2018

Who is funding the study?
MQ Transforming Mental Health (UK)

Who is the main contact?
1. Dr Amy Goodwin (public), amy.l.goodwin@kcl.ac.uk (updated 13/09/2021, previously: amy.goodwin@bbk.ac.uk)
2. Dr Emily Jones (scientific)
3. Professor Mark Johnson (scientific)

Contact information

Type(s)
Public

Contact name
Dr Amy Goodwin

Contact details
Centre for Brain & Cognitive Development (CBCD)
Birkbeck
University of London
London
United Kingdom
WC1E 7HX
+44 20 7079 0761
amy.l.goodwin@kcl.ac.uk

Type(s)
Scientific

Contact name
Dr Emily Jones

Contact details
Centre for Brain and Cognitive Development (CBCD)
Birkbeck College

Malet Street
London
United Kingdom
WC1E 7HX
+44 20 7631 6587
e.jones@bbk.ac.uk

Type(s)
Scientific

Contact name
Dr Mark Johnson

Contact details
Centre for Brain and Cognitive Development (CBCD)
Birkbeck College
Malet Street
London
United Kingdom
WC1E 7HX

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Attention control training for infants at risk of ADHD: a randomised controlled trial

Acronym
INTER-STAARS

Study objectives
The study hypotheses are the following:
1. The proposed training programme will improve attention control in infants at familial risk for ADHD
2. These effects will be mediated by changes in the executive attention system and will transfer to a range of testing contexts in the short and medium term
3. These changes in neurocognitive function will be associated with reductions in early emerging symptoms of ADHD

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES – London Central, ref: 15/LO/0407.

Study design

Phase 2 randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infants at risk for Attention Deficit Hyperactivity Disorder (ADHD)

Interventions
Training Programme:
Individual training sessions will be conducted by research assistants in the participants' homes under the supervision of an experienced postdoctoral researcher. The infant training protocol consists of a battery of gaze-contingent adaptive tasks targeting attention control. These tasks are designed to train attention control across cognitive domains that include sustained attention, working memory, visual search and inhibitory control. Tasks are designed to be attractive and enjoyable for infants, to maximise participant retention and acceptability of the intervention to families. Games are adaptive, such that they become harder as infants perform better. This maintains motivation and ensures that training is targeted at an appropriate level for individual infants.

Control Training:
The Control group will receive up to 9 weekly 'in home' sessions over three months (approximately one session per week) of infant-directed commercial videos. Set-up, procedures, audiovisual complexity and duration of clips will matched to the training condition where possible.

Intervention Type
Behavioural

Primary outcome(s)
Our primary outcome measure will be a composite measure of:
1. Cognitive control, expressed as the percentage of trials on which infants correctly anticipate the location of the target stimulus during both the learning and reversal phase
2. Disengaging visual attention as measured in the gap-overlap task by the difference in saccadic reaction times between the baseline and the overlap condition
3. Sustained attention, expressed as peak look duration during the interesting condition minus peak look duration during the boring condition (or alternatively we can use the ratio), across both home and lab-based measures. To note, in the lab-based sustained attention task only one type of stimulus is used to calculate the peak look duration

Treatment blind analysis will be carried out to assess quality of data collected during testing sessions. Therefore we will use a home-lab composite primary outcome measure score UNLESS the following conditions are not met for at least 75% of the sample:

1. Cognitive control task: each infant must have a minimum 4 trials with anticipations (either correct or incorrect) for both learning and reversal phases
2. Gap-overlap task: each infant must have a minimum of 5 valid trials per condition (baseline, gap, overlap)

3. Sustained attention: a minimum of 4 'looks' per infant during both boring and interesting phases.
4. Time between last home session and post-training lab-visit less than 4 weeks

If these conditions are not met for 75% of the sample, then we will EITHER use the home measures only (if 1, 2 and 3 are met for 75% of infants for the home battery, but 4 is not met) or the lab measures only, (if 1, 2 and 3 are not met for the home battery but 4 is met) to calculate the final composite score.
If this is not possible (e.g. 1, 2, 3 and 4 are not met for the home battery) then we will select either the lab or the home composite on the basis of which battery has the greater proportion of infants who meet criteria 1, 2 and 3.

Key secondary outcome(s))
Secondary outcome measures will include:
1. Measures of generalisation to behaviour
We will employ several behavioural measures of sustained attention and activity level at 14 months. These include:
1.1. Infant Behaviour Questionnaire (IBQ; assessment of temperament including domains such as attentional focusing, effortful control)
1.2. Toy play (duration of attention to objects)
1.3. Early Social Communication Scales (ESCS, Initiating Joint Attention and Responding to Joint Attention tasks)

These measures tap behaviours that are relevant in everyday contexts for infants. For example, the IBQ asks about a child's ability to pay attention for extended periods during book reading or interaction with a parent. Further, performance on these measures has been linked to levels of later ADHD symptoms. Thus, these measures will allow us to assess the generalisability of training effects to naturalistic contexts.

Completion date
31/01/2019

Eligibility

Key inclusion criteria
Inclusion criteria as of 12/01/2017
1. Infants will be under 14 months of age at enrolment;
2. Infants will have a first degree relative (an older sibling or a parent) with a clinical and/or research diagnosis of ADHD or a probable diagnosis of ADHD (assessed using DSM IV or V criteria). To note, depending on recruitment's rates, we may also recruit infants with an older sibling or parent with ASD;
3. Infants have agreed to take part in our affiliated STAARS project.

Screening procedure for ADHD probable diagnosis:
In order to maximise participation in the final months of recruitment the study team aim to introduce a targeted screening approach of specific populations. If an interested family will contact us about INTER-STAARS with a suspected diagnosis of ADHD for either a parent or child, we will assess eligibility using the following criteria:

Children
1. For children aged <6 years old:

A shortened version of the Conners Early Childhood (Conners, 2009) will be administered over the phone with a parent by a trained researcher. Cut-offs for inclusion will be:
1.1. Presence of 4 DSM-5 ADHD symptoms on either the inattention scale or the hyperactivity /impulsivity scale
1.2. Positive score on the impairment scale
2. For children aged >= 6 years old:
A shortened version of the Conners 3 (Conners, 2008) will be administered over the phone with a parent by a trained researcher. Cut-offs for inclusion will be:
2.1. Presence of 5 DSM-5 ADHD symptoms on either the inattention scale or the hyperactivity /impulsivity scale.
2.2. Positive score on the impairment scale.

Adults
1. A shortened version of the Conners Adult ADHD Rating Scale (CAARS, Conners, Erhart & Sparrow, 2003) will be administered over the phone by a trained researcher. The cut-off for inclusion will be:
1.1. Presence of 5 DSM-5 ADHD symptoms for either the hyperactivity/impulsivity or inattention scale.

Original inclusion criteria:
1. Infants will be under 12 months of age at enrolment;
2. Infants will have a first degree relative (an older sibling or a parent) with a clinical and/or research diagnosis of ADHD or a probable diagnosis of ADHD (assessed using DSM IV or V criteria). To note, depending on recruitment's rates, we may also recruit infants with an older sibling or parent with ASD

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Serious medical or developmental conditions, such as epilepsy, heart conditions, cerebral palsy, intellectual disability
2. Significant uncorrected vision or hearing problems;
3. Eye-tracker not able to track infants’ eyes after four consecutive attempts as measured during the pre-training home assessment

Added 12/01/2017:
4. Down Syndrome in the older sibling

Date of first enrolment
01/07/2015

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre For Brain and Cognitive Development (CBCD) (lead centre)
Birkbeck College, Malet Street
London
United Kingdom
WC1E 7HX

Study participating centre
University of Southampton
Highfield Campus
Southampton
United Kingdom
SO17 1BJ

Study participating centre
King's College London
Institute of Psychiatry, Psyschology and Neuroscience (IoPPN), De Crespigny Park
London
United Kingdom
SE5 8AF

Study participating centre
South London and Maudsley NHS Foundation Trust (SLaM)
Mausdsley Hospital, Denmark Hill
London
United Kingdom
SE5 8AZ

Study participating centre
Solent NHS Trust
Adelaide Health Centre, Western Community Hospital, William Macleod Way

Southampton
United Kingdom
SO16 4XE

Sponsor information

Organisation
Birkbeck College

ROR
https://ror.org/02mb95055

Funder(s)

Funder type
Charity

Funder Name
MQ Transforming Mental Health

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Simona Salomone (ubssal002@mail.bbk.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/12/2021	22/12/2021	Yes	No
Protocol article	protocol	28/12/2016		Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version v2.0	16/07/2019	16/07/2019	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes