

# Investigating the effects of cardio and non-cardio exercise on adults with Attention Deficit Hyperactivity Disorder (ADHD)

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| <b>Submission date</b><br>04/05/2020   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>11/05/2020 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>22/08/2023       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Attention Deficit Hyperactivity Disorder (ADHD) affects around 3% of adults and is associated with reduced attention, high levels of impulsivity, hyperactivity and altered reward learning. At present, adult ADHD is normally treated with medications (e.g. Ritalin or Adderall) but there are concerns about side effects, abuse potential and they do not work for everyone. It is therefore important to consider alternative approaches. Preliminary research with children suggests exercise may be a suitable intervention but there is a lack of controlled research in all participants and very little research at all in adults. The aim of this study is to see if cardio (cycling) and non-cardio (yoga) exercise are effective at reducing the symptoms of ADHD in adults, both alone and in combination with ADHD medication.

### Who can participate?

Adults aged 18-35 with:

1. No current or previous diagnosis of ADHD
2. A current diagnosis of ADHD but not currently receiving any drug treatment for the condition (and have not done so for 6 months)
3. A current diagnosis of ADHD and currently receiving and adhering to psychostimulant treatment for the condition

### What does the study involve?

Participants will first complete a brief online screening survey (<15 minutes). As part of the survey, participants will answer seven questions to determine their fitness to participate. If fit to participate, volunteers will be asked to answer further questions including basic demographic information (e.g. age, gender) and some questions about their typical exercise habits. The final part of the screening survey that all participants will complete includes a question asking them about any current ADHD diagnosis and ADHD symptoms. For those who report a diagnosis of ADHD, details of treatment (e.g. dose, drug) will be required. Finally, participants will be asked to provide an email address so that they can be contacted by the research team to arrange a time to visit the testing laboratory.

On arrival at the testing laboratory, the researcher will take a measure of participants' blood

pressure to confirm fitness to exercise. All participants will be asked to wear a small activity monitoring device, similar to the common 'Fitbit' watches on either their wrist or ankle during testing. Testing will be in two phases – before and after exercise – with the same computerised tests completed in both phases and aim to measure attention, impulsivity and reward learning. Brief descriptions of the tests are given below:

1. Test of attention – participants will be asked to press a letter on a keyboard to respond to a target stimulus whilst inhibiting responses to non-target stimulus.
2. Tests of impulsivity – two specific tests will be used to measure impulsivity. In the first test participants will be asked to make choices, using keyboard presses, between hypothetical rewards now or at a point in the future for several different delays e.g. 1 week, 2 weeks, 1 month, 3 months, 6 months and 1 year. In the second test, participants will be shown four decks of cards (labelled A, B, C, and D) and asked to choose 100 times from the decks with two decks giving greater gains and losses.
3. Test of reward learning – participants will be presented with one of two stimuli and asked to make a keyboard response. Shortly after the initial stimulus is presented a second stimulus will be shown, for which there are two options, one symbolic of a reward. During this task, the researchers will track participants' eye movements.

After completion of these tasks participants will be asked to either cycle with moderate intensity on an exercise bike for 10 minutes or follow an instructional yoga video for the same period. Following this, the above tasks will be completed for the second time. Participants with ADHD will also be asked to fill in a few brief medication adherence questions on a computer. In total testing should take around 2 hours and will take place in the Psychology Department at King's College London.

What are the possible benefits and risks of participating?

The data collected will provide valuable information about the effectiveness of exercise in treating ADHD and therefore has the potential to be beneficial to patients with the condition in the future. There are no direct benefits to participants for participating in this study, although those who attend and complete laboratory testing will receive an Amazon voucher as a 'thank you'. Only participants who are deemed physically fit enough to participate will be eligible to take part and therefore, the researchers don't anticipate any specific risks in taking part in the exercise. They will be also be asking about symptoms of ADHD and use of medication, where appropriate. These questions are first asked during the screening survey and it is clear this information is required in the information sheet so it is hoped that participants choosing to participate in the study will be comfortable sharing this information. If they do not, they can withdraw at any point.

Where is the study run from?

King's College London (UK)

When is the study starting and how long is it expected to run for?

September 2018 to July 2022

Who is funding the study?

Rosetrees Trust (UK)

Who is the main contact?

Dr Eleanor Dommett

eleanor.dommett@kcl.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Eleanor Jane Dommett

**ORCID ID**

<http://orcid.org/0000-0002-6973-8762>

**Contact details**

Dept of Psychology  
Institute of Psychiatry, Psychology and Neuroscience  
King's College London  
London  
United Kingdom  
SE1 1UL  
+44 (0)207 848 6928  
[eleanor.dommett@kcl.ac.uk](mailto:eleanor.dommett@kcl.ac.uk)

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

279417

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 45510, IRAS 279417

## Study information

**Scientific Title**

Investigating the effects of cardio and non-cardio exercise on adults with Attention Deficit Hyperactivity Disorder (ADHD): a randomized controlled trial

**Study objectives**

Aims:

1. To assess and compare the impact of acute cardio and non-cardio exercise on core symptoms of ADHD and key-related behaviour in unmedicated adults with ADHD in comparison to healthy control participants to establish the effectiveness of exercise as a standalone treatment for the condition.
2. To assess and compare the impact of acute cardio and non-cardio exercise on core symptoms of ADHD and key-related behaviour in medicated adults with ADHD in comparison to unmedicated adults with ADHD to establish the effectiveness of exercise as an adjunct treatment for ADHD.

## Hypotheses:

1. There will be a significant effect of cardio and non-cardio exercise on core symptoms and impairments found in ADHD.
2. There will be a difference in the extent of the effect of exercise on core symptoms and impairments found in ADHD according to whether individuals are receiving medication.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 10/04/2020, North of Scotland Research Ethics Service (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; nosres@nhs.net), REC ref: 20/NS/0053

## Study design

Randomized; Both; Design type: Treatment, Physical, Active Monitoring, Case-controlled study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

See study outputs table

## Health condition(s) or problem(s) studied

Attention Deficit Hyperactivity Disorder (ADHD)

## Interventions

Participants will first complete a brief online screening survey (<15 minutes). As part of the survey, participants will answer seven questions to determine their fitness to participate. If fit to participate, volunteers will be asked to answer further questions including basic demographic information (e.g. age, gender) and some questions about their typical exercise habits. The final part of the screening survey that all participants will complete includes a question asking them about any current ADHD diagnosis and the Adult ADHD Self-Report Scale, a short survey assessing ADHD symptomology. For those who report a diagnosis of ADHD, details of treatment (e.g. dose, drug) will be required. Finally, participants will be asked to provide an email address so that they can be contacted by the research team to arrange a time to visit the testing laboratory.

On arrival at the testing laboratory, the researcher will take a measure of participants' blood pressure to confirm fitness to exercise. All participants will be asked to wear a small activity monitoring device, similar to the common 'Fitbit' watches on either their wrist or ankle during testing. Testing will be in two phases - before and after exercise – with the same computerised tests completed in both phases and aim to measure attention, impulsivity and reward learning.

Brief descriptions of the tests are given below:

1. Test of attention – participants will be asked to press a letter on a keyboard to respond to a target stimulus whilst inhibiting responses to non-target stimulus.
2. Tests of impulsivity – two specific tests will be used to measure impulsivity. In the first test participants will be asked to make choices, using keyboard presses, between hypothetical rewards now or at a point in the future for several different delays e.g. 1 week, 2 weeks, 1 month, 3 months, 6 months and 1 year. In the second test, participants will be shown 4 decks of cards (labelled A, B, C, and D) and asked to choose 100 times from the decks with two decks giving greater gains and losses.
3. Test of reward learning – participants will be presented with one of two stimuli and asked to make a keyboard response. Shortly after the initial stimulus is presented a second stimulus will be shown, for which there are two options, one symbolic of a reward. During this task, the researchers will track participants' eye movements.

After completion of these tasks participants will be asked to either cycle with moderate intensity on an exercise bike for 10 minutes or follow an instructional yoga video for the same period. Following this, the above tasks will be completed for the second time. Participants with ADHD will also be asked to fill in a few brief medication adherence questions on a computer. In total testing should take around 2 hours and will take place in the Psychology Department at King's College London.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Attention measured using the computerised Test of Variable of Attention (TOVA) task (omission errors, accuracy, reaction time) before exercise and after exercise during the single two-hour testing session required
2. Motor impulsivity measured using the computerised Test of Variable of Attention (TOVA) task (commission errors) before exercise and after exercise during the single two-hour testing session required
3. Temporal impulsivity measured using the computerised Delay Discounting Task (indifference point, discounting function) before exercise and after exercise during the single two-hour testing session required
4. Cognitive impulsivity measured using the computerised Iowa Gambling Task (proportion of risky decisions) before exercise and after exercise during the single two-hour testing session required
5. Hyperactivity measured through actigraphy (movement in non-dominant wrist) before exercise and after exercise during the single two-hour testing session required

## **Secondary outcome measures**

Associative reward learning measured using a computerised Pavlovian conditioning task during eye tracking (reaction time, gaze position) before exercise and after exercise during the single two-hour testing session required

## **Overall study start date**

13/09/2019

## **Completion date**

31/07/2022

# Eligibility

## Key inclusion criteria

1. Adults aged 18-35 years
2. Fit enough to undertake cardio or non-cardio exercise for 12 minutes
3. Free from any physical, neurological or psychiatric conditions (besides Attention Deficit Hyperactivity Disorder for the patient groups) and learning disorders/disabilities

Participants will fall into one of the following categories in order to be eligible for the study:

1. No current or previous diagnosis of ADHD
2. Current diagnosis of ADHD but not currently receiving any drug treatment for the condition (and have not done so for 6 months)
3. Current diagnosis of ADHD and currently receiving psychostimulant drug treatment for the condition.

## Participant type(s)

Mixed

## Age group

Adult

## Lower age limit

18 Years

## Upper age limit

35 Years

## Sex

Both

## Target number of participants

Planned Sample Size: 136; UK Sample Size: 136

## Total final enrolment

159

## Key exclusion criteria

1. Diagnosis of a psychiatric or neurological disorder
2. Learning disability
3. Currently pregnant or breastfeeding
4. Medication adherence <70%
5. Currently receiving non-stimulant medication for ADHD
6. Not fit enough to safely sustain physical activity for 12 minutes
7. Blood pressure > 140/90mmHg on the day of the lab visit

## Date of first enrolment

16/09/2019

## Date of final enrolment

20/07/2022

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

### King's College London

Department of Psychology

Addison House

Guy's Campus

London

United Kingdom

SE1 1UL

## Study participating centre

### South London And Maudsley NHS Foundation Trust

Maudsley Hospital

Denmark Hill

London

United Kingdom

SE5 8AZ

# Sponsor information

## Organisation

King's College London

## Sponsor details

c/o Prof. Reza Razavi

57 Waterloo Road

Room 5.31

James Clerk Maxwell Building

London

England

United Kingdom

SE1 8WA

+44 (0)207 8483224

reza.razavi@kcl.ac.uk

## Sponsor type

University/education

**Website**

<http://www.kcl.ac.uk/index.aspx>

**ROR**

<https://ror.org/0220mzb33>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Rosetrees Trust, M875

**Alternative Name(s)**

Teresa Rosenbaum Golden Charitable Trust, Rosetrees

**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**

The outcomes of this project will be disseminated in several ways which can be broadly divided into those aimed at an academic audience and those aimed at the general public:

1. Academic audiences: The researchers plan to produce 1-2 publications in a high impact peer-reviewed journals within the field of mental health and biological sciences. They will also aim to present results at a conference within these disciplines. Finally, parts of the project may contribute to student projects and therefore appear in dissertations. The publications are unlikely to be available until 6-12 months after the end of the trial but conference presentations and student projects will be completed during the trial.

2. General public: The researchers will produce a report aimed at the general public which will be made available electronically 6-12 months after the trial ends (to coincide with any scientific publications). This will be sent to key ADHD organisations including those in the London area, where most participants will have been recruited from. For example, this will be sent to the All-Party Parliamentary Group for ADHD, ADHD Action and ADDISS. This report will also be made available via social media. In addition, the researchers will produce a short video and infographic in Autumn 2020 to describe the research aims and approach, followed summary ones at the end of the project. In both cases, these will be made available via social media.



## Intention to publish date

31/07/2023

## Individual participant data (IPD) sharing plan

The anonymised datasets generated and analysed during the current study will be stored, for at least 4 years, in a publicly available repository (King's Research Data Management system) from when the results of the study are published. All datasets will be available in easily accessible formats (e.g. csv) and accompanied by published metadata with a unique DOI. The availability of data via a public repository is explicitly stated in the Participant Information Sheet and participants must confirm that they have read and understood this as part of the consent procedures.

## IPD sharing plan summary

Stored in publicly available repository

## Study outputs

| Output type                                   | Details    | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | version V1 | 30/03/2020   | 11/05/2020 | No             | Yes             |
| <a href="#">Protocol file</a>                 | version V1 | 30/03/2020   | 11/05/2020 | No             | No              |
| <a href="#">Results article</a>               |            | 02/02/2023   | 28/04/2023 | Yes            | No              |
| <a href="#">HRA research summary</a>          |            |              | 28/06/2023 | No             | No              |