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

Submission date
04/05/2020

Recruitment status
No longer recruiting

Registration date
11/05/2020

Overall study status
Completed

Last Edited
22/08/2023

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Scientific

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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.
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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 actiography (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

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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?
Participant information sheet	version V1	30/03/2020	11/05/2020	No	Yes
Protocol file	version V1	30/03/2020	11/05/2020	No	No
Results article		02/02/2023	28/04/2023	Yes	No
HRA research summary			28/06/2023	No	No