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

**Exercise and Attention Deficit Hyperactivity Disorder**

**This protocol has regard for the HRA guidance and order of content.**

**FULL STUDY TITLE**

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

**SHORT STUDY TITLE**

Exercise and Attention Deficit Hyperactivity Disorder

**RESEARCH REFERENCE NUMBERS**

|  |  |
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# I. FUNDING AND SUPPORT IN KIND

|  |  |
| --- | --- |
| **FUNDER(S)**  (Names and contact details of ALL organisations providing funding and/or support in kind for this study) | **FINANCIAL AND NON FINANCIALSUPPORT GIVEN** |
| **Rosetrees Trust** | **£59,282** |
| **King’s College London** | **Facilities for conducting the research study** |
| **South London and Maudsley NHS Foundation Trust** |  |

# II. ROLE OF TRIAL SPONSOR AND FUNDER

King’s College London is the sponsor of the study, being responsible for conducting the research procedures as described in the protocol, analyses, interpretation and dissemination of findings.

South London and Maudsley NHS Foundation Trust is the co-sponsor of the study and is responsible for arranging the initiation and management of this research, taking responsibility for ensuring that appropriate standards, conduct and reporting are adhered to regarding its facilities and staff involved with the project.

Rosetrees Trust is the funder of the study and is responsible for funding the research study to meet the objectives and recruitment target detailed in the funding application.

# 1 BACKGROUND

ADHD is the most common behavioural disorder, characterised by inattention, impulsivity and hyperactivity [1]. Subsequently ADHD is associated with reduced quality of life in patients and their families [2]. Until recently, ADHD was considered a childhood condition, affecting 6% of children [3]. However, it is now recognised that 3% of adults worldwide experience ADHD and the childhood and adult cohorts are distinct i.e. adults with ADHD are not simply children with it who grew up [4, 5]. This suggests that previous research conducted with children may not be as applicable to adults as previously thought. Given the high prevalence and significant impact of ADHD, it is imperative that we can understand and effectively treat this condition in both adults and children.

Psychostimulants (e.g. amphetamine and methylphenidate) are the most effective treatments available for all ages, reducing symptoms in >80% of patients [6-8]. The exact mechanisms of action of these drugs in ADHD is unclear but their therapeutic effect is believed to arise primarily through actions to increase dopamine levels [9,10]. However, whilst effective, they have various side effects ranging from insomnia to tachycardia and psychosis [11]. There are also concerns that the drugs may be abused [12, 13]. Research has found that 50% of adults with ADHD give away or sell their psychostimulant medication and a further 30% misuse it themselves [14], indicating these treatments do carry risk of drug abuse. Whilst non-stimulant treatments exist (e.g. atomoxetine), the response rate is considerably lower, with less than 67% of patients responding [15] and many still experience side effects, albeit less severe (e.g. headaches) [11]. Given the limitations of current drug treatments, other therapeutic approaches are often examined. Most recently, exercise has been proposed as an additional or alternative safe and effective treatment [16].

Exercise can be categorised as cardio or non-cardio [16]. Cardio is associated with increased heart rate, perspiration and ‘getting out of breath’ and includes activities such cycling. By contrast, non-cardio involves tranquil activities such as yoga. Both types of exercise are associated with physical and cognitive gains in healthy individuals [17-19]. The benefits of exercise may arise through several mechanisms but there is evidence demonstrating that exercise may have similar effects to psychostimulants. For example, cardio exercise is known to increase dopamine levels [20] and alteration to dopaminergic markers have been found in the animal models after exercise [21]. In addition, several studies have now reported an increase in dopamine after meditation or yoga in healthy adults [22, 23]. The fact that cardio and non-cardio exercise can increase dopamine levels suggests that it may be an effective treatment for ADHD.

**Cardio exercise**: Several reviews have examined the effects of exercise on children with ADHD and, the most comprehensive concluded that even acute cardio exercise improves key measures of cognition including impulsivity and attention [16]. This is supported by evidence from animal models of ADHD showing that cardio exercise can improve symptoms both by itself [24] and in combination with methylphenidate [25-28] or atomoxetine [32]. There is little research on the impact of cardio exercise on adults with ADHD. Several correlational studies suggest that higher levels of cardio exercise are associated with reduced symptoms but these studies have relied on self-report measures and small sample sizes [30, 31] and it is impossible to determine the direction of effect or causality in correlational studies. Only one study to date has used a non-correlational design and found general cognitive and motivational improvements [32]. While promising, the sample size was very small and specific ADHD-related behaviours were not examined. There is evidence from healthy adults for improvements in cognition after cardio exercise [33]. Furthermore, our own pilot data reveals that just 10 min of cycling at medium intensity significantly reduces impulsive decisions in healthy adults with high impulsivity as measured on the ADHD self-report scale. Therefore, whilst research in this field shows potential, more robust and specific tests are required in larger samples of those with ADHD to determine whether cardio exercise can help reduce symptoms of ADHD.

**Non-cardio exercise**: Investigations into the effects of non-cardio exercise are in the very early stages and often lack a rigorous study design [16]. For example, one study reported reductions in hyperactivity and inattention after tai chi [34] and another reported improvements in attention after a walk [35] in children with ADHD but in both cases, additional variables were uncontrolled, making it difficult to draw firm conclusions. Another study found positive effects of yoga on attention in children [36] but the authors themselves acknowledged that the sample size was too small to draw firm conclusions. Data in adults is even more scarce, with only one study looking at the effects of Whole Body Vibration (sitting or standing on a vibrating plate) on adults with ADHD. In this study there were benefits for attention in both those with ADHD and healthy adults [37]. Given the nature of this kind of exercise (i.e. yoga or tai chi) there are no animal studies available.

Based on the research to date, exercise may offer an efficacious and safe treatment for adult ADHD, even when conducted acutely. However, research in adult populations, who are now known to be distinct from the childhood ADHD cohort, is lacking and what research has been conducted has focused on cardio exercise and correlational studies. Given this, the proposed research aims to investigate the impact of acute cardio and non-cardio exercise in adults with ADHD.

# 2 RATIONALE

## 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 psychostimulant 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 on 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.

# 3 OBJECTIVES AND OUTCOME MEASURES

## 3.1 Primary objectives

The purpose of the study is to assess the impact of two different types of exercise: cardio (cycling) and non-cardio (yoga) on attention, impulsivity and hyperactivity. We aim to see if these forms of exercise are effective in reducing the symptoms of ADHD in adults, both alone and in combination with ADHD medication.

## 3.2 Secondary objective

In addition to assessing the core symptoms of ADHD we will also assess reward learning, a form of learning, which is thought to be altered in ADHD.

## 3.3 Outcome measures

Test of Variables of Attention (TOVA) – inattention (omission errors); motor impulsivity (commission errors)

Delay Discounting Task (DDT) – temporal impulsivity (indifference points).

Iowa Gambling Task (IGT) – cognitive impulsivity (index of long-term consequences)

Actigraphy - hyperactivity (ZCM – frequency of movement, PCM – intensity of movement)

Pavlovian conditioning with eye-tracking – sign-tracking and goal-tracking indexes based on pre-defined regions of interest.

## 3.4 Primary outcomes

Test of Variables of Attention (TOVA) – inattention (omission errors); motor impulsivity (commission errors)

Delay Discounting Task (DDT) – temporal impulsivity (indifference points).

Iowa Gambling Task (IGT) – cognitive impulsivity (index of long-term consequences)

Actigraphy – hyperactivity (ZCM – frequency of movement, PIM – intensity of movement)

## 3.5 Secondary outcome

Pavlovian conditioning with eye-tracking – sign-tracking and goal-tracking indexes based on pre-defined regions of interest.

## 3.6 Table of outcomes

|  |  |  |
| --- | --- | --- |
| **Objectives** | **Outcome Measures** | **Timepoint(s) of evaluation of this outcome measure (if applicable)** |
| **Primary Objective** To assess the impact of two different types of exercise: cardio (cycling) and non-cardio (yoga) on reducing attention, impulsivity and hyperactivity in adults with ADHD, both alone and in combination with ADHD medication (psychostimulants or non-stimulants). | TOVA, DDT, IGT, actigraphy | During the laboratory visit, before and after exercising for 10 minutes. |
| **Secondary Objectives** To assess reward learning, a form of learning, which is thought to be altered in ADHD. | Pavlovian conditioning with eye-tracking | During the laboratory visit, before and after exercising for 10 minutes. |

# 4 TRIAL DESIGN

Controlled study without randomisation. The study involves filling in an online survey and attending a laboratory visit, where participants are asked to do an eye-tracking task and cognitive tests on a computer before and after exercising for 12 minutes.

# 5 TRIAL SETTING

This is a single centre research study, taking place in the Department of Psychology, King’s College London.

# 6 PARTICIPANT ELIGIBILITY CRITERIA

## 6.1 Inclusion criteria

The study is recruiting adults aged 18-35 years, who are fit enough to undertake cardio or non-cardio exercise for 12 minutes. All participants will be 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.

## 6.2 Exclusion criteria

Participants are not eligible to take part if they have a diagnosis of a psychiatric or neurological disorder, if they have a learning disability, if they are currently pregnant or breastfeeding, if their medication adherence is <70%, if they currently receive non-stimulant medication for ADHD, if they are not fit enough to safely sustain physical activity for 12 minutes, if their blood pressure is >140/90mmHg on the day of the lab visit.

# 7 TRIAL PROCEDURES

Participants will first complete a brief online screening survey (<15 mins). As part of the survey, participants will answer 7-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 once their screening survey answers has been reviewed and they have been confirmed as eligible to participate.

On arrival to 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 ‘fit bit’ 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 we 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 12 mins 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.

## 7.1 Recruitment

Participants will be recruited through institutional volunteer recruitment channels. The institutional recruitment network at King’s is highly effective for recruiting healthy participants and those with conditions such as ADHD (which is relatively common in the student population). However, we will also advertise the study via groups such as the UK Adult ADHD network (https://www.ukaan.org/otherresearch.htm) which allows research advertisements and has a long-standing link to King’s College and the Institute of Psychiatry, Psychology and Neuroscience.

If interested in the study, participants will complete the short online questionnaire, after which they will be contacted by the Research Assistant who will confirm eligibility. If eligible, the Research Assistant will contact participants to schedule a laboratory visit.

The study is also in the process of obtaining NHS ethics. If granted, some participants will be first approach by their care coordinator, who will pass on the participants' details if they are interested in participating and only with their consent.

## 7.1.1 Participant identification

Currently, potential participants are recruited through (1) advertisements via e-mail circulars, social media platforms and flyers at King's College London, and (2) advertisements via ADHD local/national organisations. The Research Assistant manages all recruitment.

The research team seeks to expand the study's recruitment avenues to the NHS through (a) collaborations with SLaM clinicians and (b) C4C using the Clinical Record Interactive Search (CRIS) system. The Research Assistant will initiate contact with relevant care coordinators and will screen relevant CRIS data.

**SLaM collaborations**: The Research Assistant on the study will be in regular contact with SLaM care coordinators and potentially be in attendance of relevant clinical meetings. The RA will inform the collaborating clinicians of the study's inclusion and exclusion criteria, such that the clinicians may be able to identify certain patients who might fit the criteria. In this case, the patient will be first approached by the care coordinator and, should they express their interest in finding out more about the research study and consent to being contacted by the research team, the RA will initiate contact via telephone or e-mail and offer more information about the study.

**C4C using CRIS**: In the case of C4C screening via CRIS, the RA will have access to anonymised data of patients who have consented to being contacted about potentially participating in research. If the RA identified a suitable participant, the RA will initiate contact with the patient's care coordinator to liaise with regards to contacting the patient.

The research team will only approach service users who have consented to being contacted with regards to research studies, either through allowing their anonymised data to be available for screening on the CRIS database or through agreeing to being contacted by the RA following an initial contact with their care coordinator who will ask them about their potential participation in this research study. No personal data will be accessed without the explicit consent of the service user and their care coordinator. If included in the study, the service users' personal data will be immediately anonymised for analysis.

## 7.1.2 Screening

All participants are asked to fill in a short online screening survey before they are invited for the laboratory visit.

## 7.1.3 Payment

Participants who attend and complete the laboratory for testing will receive a £22 Amazon voucher as a ‘thank you’ for participating. This is based on the standard rate that King's requires participants are paid per hour.

## 7.2 Consent

Informed consent will be taken from all participants, twice. As the study involves two parts (an online survey and laboratory testing), written consent is first sought as part of the online survey. Then, consent is sought again upon arrival at the testing facility, both verbally and as part of an online form.

On both occasions, participants are first presented with a written participant information sheet which explains in detail the study and the various tasks the participant will be undertaking (there is a written participant information sheet in the online survey and participants are also given a printed copy of the information sheet upon arrival at the scanning facility). Informed consent is sought by the Research Assistant, who also explains the details of the study to each participant verbally during the laboratory visit, on top of providing them a copy of the information sheet, to make sure that all participants fully understand the requirements of the study. All participants are encouraged to ask any questions they may have with regards to the study.

Participants can take as long as they need to consider participation in the study, as the information sheet is openly available at the beginning of the online survey, which the participants complete in their own time. At this point, the research team encourages participants to get in touch should they have any questions. If consent is recorded and the participant is eligible to be invited for a lab visit, they will be contacted by the Research Assistant who will schedule the visit at least 24 hours apart from the time the online response was recorded. Upon arrival at the research facility, the Research Assistant checks with each participant if they are still happy to take part in the study.

## 7.3 Trial assessments

|  |  |  |  |
| --- | --- | --- | --- |
| **Intervention or procedure** | **Number of times it is administered** | **Average time taken per intervention/procedure** | **Person conducting the interventions/procedures and where they take place** |
| Online questionnaire (includes informed consent) | 1 | 10m | The online questionnaire is hosted on an online survey builder website (i.e. Qualtrics) and can be taken remotely. |
| Informed consent (again, at lab visit) | 1 | 10m | Consent will be sought by a Research Assistant/postgraduate taught student and the lab visit will take place at Addison House, Guy's Campus, King's College London, in a testing laboratory. |
| Pavlovian Conditioning with Eye Tracking (performed using specialist eye tracking equipment) | 2 | 10m | This task is conducted by the Research Assistant/postgraduate taught student at Guy's Campus, twice (before and after exercising) |
| Delay Discounting Task (computer-based) | 2 | 10m | This task is computer-based and performed under monitoring by the Research Assistant/postgraduate taught student at Guy's Campus. The task is performed twice (before and after exercising). |
| Iowa Gambling Task (computer-based) | 2 | 10m | This task is computer-based and performed under monitoring by the Research Assistant/postgraduate taught student at Guy's Campus. The task is performed twice (before and after exercising). |
| Test of Variables of Attention (computer-based) | 2 | 22m | This task is computer-based and performed under monitoring by the Research Assistant/postgraduate taught student at Guy's Campus. The task is performed twice (before and after exercising). |
| Cardio (cycling on an indoor stationary bike) or non-cardio (guided yoga) exercise | 1 | 12m | Exercising is overseen by the Research Assistant/postgraduate taught student and takes place on Guy's Campus. |
| Blood pressure monitoring | 2 | 5m | Blood pressure is measured by the Research Assistant/postgraduate taught student in a laboratory in Addison House, Guy's Campus. Blood pressure is measured twice before any procedures are initiated to determine participant's fitness to exercise. |
| Heart rate monitoring | 2 | 2m | Heart rate monitoring is measured by the Research Assistant/postgraduate taught student in a laboratory in Addison House, Guy's Campus. Heart rate is measured twice: once before exercising and again after exercising. |

Total time to complete the study: approximately 120 minutes.

## 7.4 Qualitative assessments

Not applicable.

## 7.5 Withdrawal criteria

Participants are free withdraw at any point of the study, without having to give a reason.

Withdrawing from the study will not affect participants in any way.

Participants can withdraw their data up to three months after completion of testing, after which their anonymised data will have been included in analyses and interim reports.

If they choose to withdraw from the study, we will not retain the information they have given thus far.

## 7.6 End of study

Participants’ involvement with the study end immediately after completing their laboratory assessments and receiving their reimbursement.

# 8 Concomitant medication

The current study is investigating the effects of exercise on ADHD core symptoms in medicated and unmedicated individuals with a diagnosis of ADHD. Participants are instructed to take their medication as usual. There

## 8.1 Assessment of medication adherence

While the current study does not involve the administration of any medication, the study is measuring medication adherence of the ADHD medication that some participants are ordinarily taking. This is done twice – once in the online screening survey and then again during the laboratory visit. To measure adherence, participants are asked how many tablets they were supposed to take during the past 2 weeks and how many they took.

# 9 STATISTICS AND DATA ANALYSIS

## *9.1* Sample size calculation

There is no existing data to calculate sample size. However, a power analysis assuming a medium effect size and power of 0.95 requires 41 participants per group (246 in total). We have planned and costed for this +10% as is typical in human work where some individuals may be excluded (e.g. incomplete data set). This gives a maximum of 271 participants.

## 9.2 Planned recruitment rate

Based on availability of shared facilities, it is expected that, on average, 3-6 participants will be tested each week.

## 9.3 Statistical analysis plan

### 9.3.1 Primary and secondary outcome analysis

To achieve the study's objectives, we will adopt a 3 x 2 x 2 factorial design. Factor 1, ‘ADHD Status’, is a between-subjects factor and consists of four distinct participant groups (healthy controls, unmedicated ADHD, medicated ADHD on psychostimulants, medicated ADHD on non-stimulants). Factor 2, also between-subjects, is ‘Exercise’ and consists of two conditions: cardio and non-cardio. The final factor is within-subjects and is the ‘Time’ at which measures (primary and secondary outcomes) are collected i.e. before and after exercise.

Data analysis will use parametric methods, typically mixed ANOVA, after normality checks and any necessary transformations.

# 10 Participant population

Adults aged 18-35 years with or without a diagnosis of ADHD. Those who have a formal diagnosis of ADHD will be eligible to participate if they are receiving stimulant medication or if they are currently unmedicated (and have been so for at least 6 months).

# 11. DATA MANAGEMENT

## 11.1 Data collection tools and source document identification

## Participant files are produced during each laboratory visit on paper by the Research Assistant. These are immediately transcribed electronically and stored on a restricted-access OneDrive for Business account which is password-protected and accessible only to the immediate research team. All participant files contain anonymised, unidentifiable data. Paper copies of the participant files are stored securely in a locked cupboard in Addison House. Only the Research Assistant and Principal Investigator have access to this cupboard.

## 11.2 Data handling and record keeping

## Participants' anonymised personal data is securely stored on a restricted-access OneDrive for Business folder to which only the immediate research team has access. These files are also stored on password-protected university, personal and laptop computers as necessary for analysis. However, the master spreadsheet which contains the participants' e-mail addresses correlated with their unique IDs is password-protected and only the RA and PIs have access to it. The password is periodically changed as well.

## Furthermore, participants' files containing information such as IDs, blood pressure and task order (as the order of the tasks is counterbalanced) is securely locked in a drawer in Addison House, Guy's Campus to which only the RA and PI have access with a key.

## 11.3 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections- in line with participant consent.

## 11.4 Archiving

The funder has no specific data retention policy and therefore all data will be securely stored in an anonymised form for five years after publication. Should a suitable online data repository be available, a full set of anonymised data will be placed on the platform to allow future accessibility.

# 12 ETHICAL AND REGULATORY CONSIDERATIONS

## 12.1 Research Ethics Committee (REC) review& reports

The study has already received ethical clearance from the Psychiatry Nursing and Midwifery Research Ethics Subcommittees (PNM RESC) under the reference number LRS-18/19-13264.

The study will also be reviewed by the NHS ethics committee and health research authority.

## 12.2 Peer review

The scientific quality of the research has been assessed by the funder's scientific panel, and sent for peer review to external reviewers who specialise in ADHD research. The peer-review process was undertaken as part of the competitive funding application and passed. The quality of the research has also been assessed within the research team, between the Principal Investigator and the co-investigators (at King's College, Sheffield University and Sussex University).

## 12.3 Public and Patient Involvement

People with lived experiences will be involved in undertaking the research and dissemination of findings. Our research team will attend the next meeting of the Young People’s Mental Health Advisory Group. The members of the group are aged 16-26, which overlaps very well with our target sample (18-35). We are hoping that we can discuss our project in more detail and feedback their advice into how we are conducting the study, how can we make the project more enjoyable for individuals with lived experiences of ADHD and what possibilities of dissemination are optimal for reaching a larger, more diverse audience.

## 12.4 Data protection and patient confidentiality

Data will be processed in accordance with the General Data Protection Regulation (GDPR, 2018) and the Data Protection Act (2018).

* On receipt of screening survey data, email addresses will be removed from the dataset and replaced with a participant ID, meaning screening data will be stored anonymously. This ID will then be used for all data collected. Email addresses will be stored separately to allow participants to be contacted for booking in testing times. During the study all data will be stored on secure university servers, accessible to only the research team.
* At the end of the study, email addresses will be deleted, and fully anonymised data will be stored on the university servers for up to five years after publication of the work, accessible only to the researchers. Should a suitable online data repository be available, a full set of anonymised data will be placed on the platform to allow future accessibility.
* Participants will not be identifiable from any outputs of the project (e.g. report).

The only individuals who will have access to the personal data of the participants are the Research Assistant and Principal Investigators. Undergraduate and postgraduate students will only have access to fully anonymised datasets.

The data generated by the study will be analysed by the Research Assistant, Principal Investigators and undergraduate and postgraduate students. All datasets will be fully anonymised. Data analysis will be mostly performed at Addison House, Guy's Campus, King's College London. However, due to the nature of the study, fully anonymised datasets may be used by the research team on their personal, password-protected computers.

All data will be fully anonymised for analysis. The personal information that will be published will be age, sex, handedness and years of education, which will represent group averages and will not refer to individual participants. Participants' IDs will not be published.

The Research Assistant will act a custodian for the data generated by the study. Contact details are:

**Miss Larisa Dinu** (Research Assistant)

Qualifications: BSc Psychology (1st class), MSc in Psychiatric Research (Distinction), GCP training

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## 12.5 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

There is no conflict of interest.

## 12.6 Indemnity

The sponsor, King's College London, will take primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate management, design, conduct and reporting. King's College London provides cover under its No Fault Compensation Insurance, which provides for payment of damages or compensation in respect of any claim made by a research subject for bodily injury arising out of participation in human volunteer studies (with certain restrictions).

The co-sponsor, South London & Maudsley NHS Foundation Trust, take ultimate responsibility for arranging the initiation and management of this research, and will take responsibility for ensuring that appropriate standards, conduct and reporting are adhered to regarding its facilities and staff involved with the project.

## 12.7 Access to the final study dataset

The final trial dataset will be fully anonymised. The Principal Investigator, Research Assistant, Co-Investigators and the funder will have access to the final dataset. A copy of the anonymised dataset might be published on an online data repository if a suitable one becomes available.

# 13 DISSEMINIATION POLICY

## 13.1 Dissemination policy

The results will be disseminated though internal reports, peer-reviewed journals and at national and international conferences. This research study will lead to the generation of intellectual property, which will be the property of the Principal Investigator.

## 13.2 Authorship eligibility guidelines and any intended use of professional writers

### Authorship will be granted to members of the research group who have made an important contribution to the conduct, analysis and dissemination of the study’s findings.

# 14 REFERENCES

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