

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number: HR-19/20-14336



YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

AUTIMM Study – Autism Microbiota Mechanisms Study

I would like to invite you to participate in this original research project at King's College London. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. You should only agree to take part in the study if, having read the following information, you are happy that you understand it and wish to participate. Choosing not to take part will not disadvantage you in any way. Please ask us if there is anything that is not clear or if you would like more information or time to decide.

What is the purpose of the study?

Autism Spectrum Disorder (ASD) is primarily considered a condition affecting the brain, however evidence increasingly implicates ASD as a 'whole systems condition', with symptoms and features in the peripheral nervous system, immune system and digestive system. Of particular note is the high rate of gastrointestinal symptoms, which are present in roughly half of adults with ASD and which correlate positively with ASD severity. Furthermore, there is evidence of disruption of the gut microbiota (GM) – the community of microorganisms living in the gut.

The relationship between gastrointestinal symptoms, the GM and the clinical presentation of autism is unclear. This is problematic because a better understanding of gut-brain communication in ASD is crucial in the development of novel treatments for gastrointestinal symptoms and/or core autistic symptoms.

Therefore, we plan to study the gut bacterial composition of participants with and without ASD and with and without symptoms of gastrointestinal symptoms. We will also investigate some of the gut-brain communication pathways by examining levels of various neurotransmitters and inflammation markers in the blood and by measuring the activity of your vagal nerve (done by measuring heart rate and breathing rate).

Why have I been invited to take part?

We are looking for healthy male and female adults between the ages of 18-50 years. You may be eligible if you can answer "yes" to the following statements:

- English is my first language
- I do **not** have a major mental illness (e.g. psychosis) or a learning disability*
- I have **no** history of alcohol/drug/medication abuse
- I am **not** taking medication directly affecting the serotonin system (such as selective serotonin reuptake inhibitors (SSRI's) e.g. citalopram or fluoxetine)

- I do **not** have a genetic disorder associated with ASD (e.g. fragile X syndrome, 22q11.2 deletion syndrome)
- I have **not** been on antibiotic medication during the last month

*specific learning difficulties (e.g. dyslexia) are not included in the term learning disability.

What will happen if I take part?

The study takes place during one visit to King's College London Guy's Campus. Additionally, there is an online questionnaire to complete at your convenience and a stool sample which you can do at home. If you do not have access to the internet, we can provide a paper copy of the questionnaire.

Screening questionnaire

When you have read this information sheet and if you decide you might like to take part in the study, you would initially be screened for eligibility according to our inclusion and exclusion criteria through responses to a questionnaire. A researcher may call you to clarify your responses. If you are eligible, we would invite you to a study visit at Guy's Campus and send you a link to the online questionnaire (or a paper copy). At this point, a member of the study team will ask to call you to:

- Explain the study to you in complete details
- You would have the opportunity to ask any questions before you decide if you would like to participate
- You would be asked to provide consent by signing a consent form
- If you consent, we would enrol you in the study. You will be given a copy of the consent form to keep

Study visit

The study visit (approx. 2hrs) would be booked for your convenience. When you arrive we will:

- We will measure your weight, height and body composition
- We will measure your cognitive functioning related to autism. This is done through playing computer tasks and answering some questions from the researcher
- We will measure your heart rate and respiration rate by attaching three electrodes to your skin and a belt around your abdomen.
- Take a blood sample (approximately 16mL -> 2 tablespoons)
- Take a saliva sample (to measure oral microbiota)
- Provide you with a stool collection kit for collection of a stool sample to be returned by free post in the mail.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part, we will ask you to sign an online consent form and you will be given a copy of this consent form to keep.

Incentives

To compensate you for your time, you will receive £20 upon completion of the study.

BSc Psychology students may choose to take part in this study as part of Participation as Coursework option for the module 'Inspirational Research', in which case the study will contribute a total of 2.5 hours to their Research Participation as Coursework portfolio for the module.

What are the possible risks of taking part?

The risk associated with the work is minimal. Venepuncture (taking a blood sample) may cause a brief slight discomfort, and there may be a risk of bruising.

Some participants may experience slight discomfort, a small amount of anxiety and/or fatigue during the cognitive, physiological and/or biosampling parts of this study. To minimise this, you will be 1) offered as many breaks as you require, 2) the chance to be accompanied by a familiar person during the visit and 3) privacy when providing the saliva sample.

What are the possible benefits of taking part?

Although you personally will not receive any direct benefit from this project, other individuals with ASD, their family members and future generations may benefit from this study. At this stage the research results have no direct clinical use. For this reason, we will not provide any information on your individual results.

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR).

- Electronic data will be securely stored on an encrypted hard drive at King's College London. Physical copies of data and biological samples will be stored in secure, lockable cabinets/fridges in restricted access offices/labs.
- All data will be stored anonymously. It will not be possible to identify participants in the final report.
- In accordance with the College's Records and Data Retention Schedule, data will be retained for 7 years from the completion of the study.

- With your consent, data will be shared with the Centre for Host-Microbiome Interactions at the Faculty of Dentistry, Oral and Craniofacial Sciences, King's College London, UK.
- With your consent, blood samples will be sent outside of the EU to our collaborators at the Laboratory of Developmental Neurochemistry, Yale Child Study Center and the Department of Laboratory Medicine, Yale University School of Medicine, USA. This lab is a world leading centre for the study of blood neurochemistry. Only anonymised samples will be sent – samples cannot be used to identify individual participants. King's College London and Yale have a material transfer agreement in place which ensures that the data continues to be held in compliance with UK data protection standards (GDPR).

Data Protection Statement

The data controller for this project will be King's College London (KCL). The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a 'task in the public interest' You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King's College London Data Protection Officer Mr Albert Chan info-compliance@kcl.ac.uk. If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk.

What if I change my mind about taking part?

You are free to withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way. You are able to withdraw your data from the study up until **31st March 2022** after which withdrawal of your data will no longer be possible due to the data being anonymised. If you choose to withdraw from the study we will not retain the information you have given thus far

What will happen to the results of the study?

The data obtained we obtain from you will be collected and analysed at King's College London. DNA information will be analysed from the faecal samples in order to determine the composition of bacteria in the gut. This data will be kept for a period of 10 years following publication of study results to allow for additional analyses. After this time all data will be destroyed. Data will be presented together for all of the participants, thus, there will be nothing that would identify an individual. You will not be identifiable in any part of the work. The results are intended to be published in a scientific journal, presented at conference meetings, as well as written up for BSc, MSc and PhD theses.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact me using the following contact details:

Dr James L. Findon
Lecturer in Psychology (education)
Department of Psychology, 2nd floor, Addison House
Guy's Campus, London SE1 1UL
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What if I have further questions, or if something goes wrong?

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

The Chair
Psychiatry, Nursing and Midwifery Research Ethics Subcommittees (PNM RESC)
Research Ethics Office
Room 4.16/ 4.16A Waterloo Bridge Wing
Franklin Wilkins Building
Waterloo Road
London
SE1 9NH
rec@kcl.ac.uk

Thank you for reading this information sheet and for considering taking part in this research.