Aliya Warden
PhD student
Telephone: 07557 028 358
Email: ACH722@bham.ac.uk

Dr Craig McAllister
Assistant Professor in Motor Control
Telephone: 0121 414 5816
Email: c.j.mcallister@bham.ac.uk

Dr Hayley MacDonald
Associate Professor in Motor Neuroscience
Email: Hayley.Macdonald@uib.no

Dr Damian Cruse
Associate Professor in Psychology
Email: d.cruse@bham.ac.uk

Participant Information Sheet

Project title: Examining the neural mechanisms underlying impaired impulse control in Parkinson's disease

We would like to invite you to join a research study. Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The purpose of this study is to examine measures at the level of the muscle and brain which may be related to impulse control. Impulse control is the ability to stop and think before acting on immediate urges, which is important when making decisions. In session 1, we will record your brain activity using electroencephalography (EEG) while you respond to a task presented on a computer screen by pressing/lifting two switches. In session 2, we will use transcranial magnetic stimulation (TMS) and record your muscle responses during the same task. By analysing how you respond in the task, we will be able to further understand the brain networks that support impulse control.

Why have I been invited?

We are recruiting two distinct groups of people with Parkinson's disease: one group who are not yet taking medication, and one group who are. We are asking you to think about joining this study because either**: you have Parkinson's disease** AND **i) are not yet taking medication** OR **ii) are taking ropinirole**, which can help us understand how changes during Parkinson's disease and medication can affect impulse control.

If you have Parkinson's disease, you may be eligible to participate if:

- You are between 40-80 years of age.
- Other than Parkinson's disease, you have no history of neurological illness (including mild cognitive impairment and dementia).
- You have normal or corrected-to-normal vision (e.g., glasses).

- You are either **i) not yet taking medication** OR **ii) taking ropinirole as part of your medications** (also known as Requip, Repinex, Aimpart, Ippinia, Ralnea, Raponer, Ropilynz, Ropiqual and Spiroco).
- You do not suffer from arthritis or hand pain that would prevent you from performing repetitive hand movements.

Do I have to take part?

No. It is entirely up to you. Participation is entirely optional, and choosing not to participate will have no impact on your medical care or legal rights.

What does this study entail?

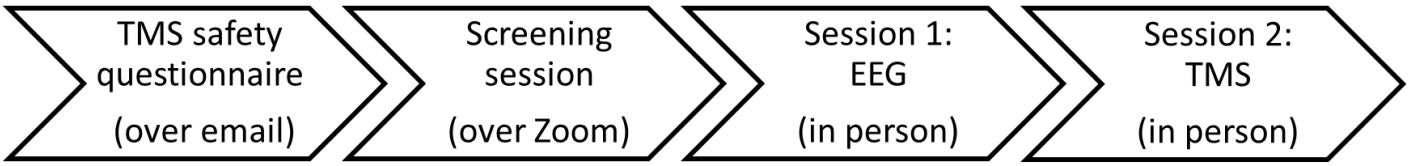
Screening:

You will first complete a brain stimulation safety questionnaire over email to check it is safe for you to undergo stimulation. We will then schedule an online screening session via Zoom, which will last around 30 minutes. You will complete the Montreal Cognitive Assessment, which evaluates cognitive function, to ensure you are eligible to participate. We will ask if you would like to know the outcome of the Montreal Cognitive Assessment. In addition, you will have the opportunity to see the laboratory and ask any questions. If you are not eligible to take part in the study, your data will be removed.

Initial steps:

If the screening session shows that you are eligible to participate, you will be asked to come to laboratories at the University of Birmingham, where a member of our research team will discuss the study with you and answer any questions you may have. If you are still happy to take part, we will ask you to sign the consent form. If relevant, we will also ask you to provide your medication information, including whether you are taking any medication for Parkinson's disease and what medication you have been prescribed, as well as information on dosage and duration. We will inform your GP that you are taking part in the study.

You will be invited to take part in two sessions which will each last approximately 3 hours. The two sessions will start in the morning (starting anytime between 9am and 11.30am) on two separate days. We will schedule the sessions on days convenient to you, with both sessions usually taking place within one month.



Flowchart of the study progression

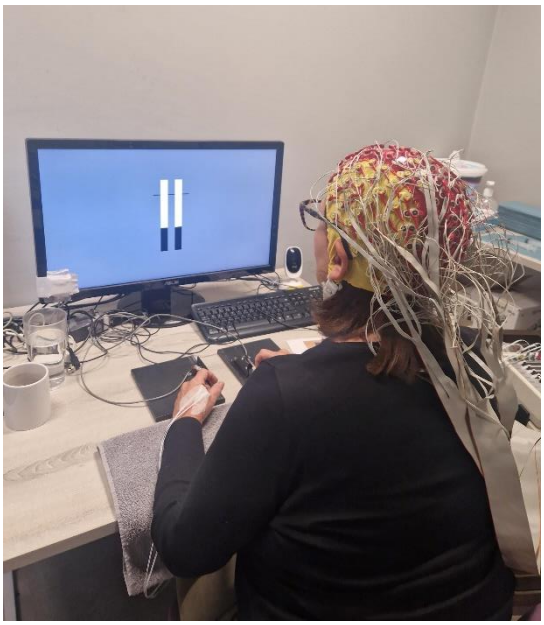
Movement task:

In each study session, you will also be asked to complete a computer-based movement task. This task will involve pressing and releasing switches with your index fingers in response to a task presented on a computer screen. You will be seated comfortably during the task. To help reduce tiredness and ensure you are comfortable during the session, we will include regular breaks, provide glasses of water, and perform seated stretches e.g., ankle and shoulder rolls.

We will undertake several assessments while you are in the labs. The researcher will explain the specifics of the study when you are ready to begin. If you have any questions at any time, please feel free to ask.

Session 1 – EEG:

The first session will take place at the Centre for Human Brain Health, University of Birmingham. We will set up an EEG recording to record your brain activity while you perform the movement task. This involves wearing a cap that is mounted with sets of electrodes that can record the small electrical signals that are constantly being generated by your brain. These electrodes can only record, and do not stimulate in any way. To record the signal from your brain, saline gel will be placed under each electrode. This washes out easily, and hair-washing facilities (including shampoo, towels, hair dryer and comb) will be made available to you after the session. We will also apply electrodes to each hand using saline gel and tape to record your muscle activity via electromyography (EMG).



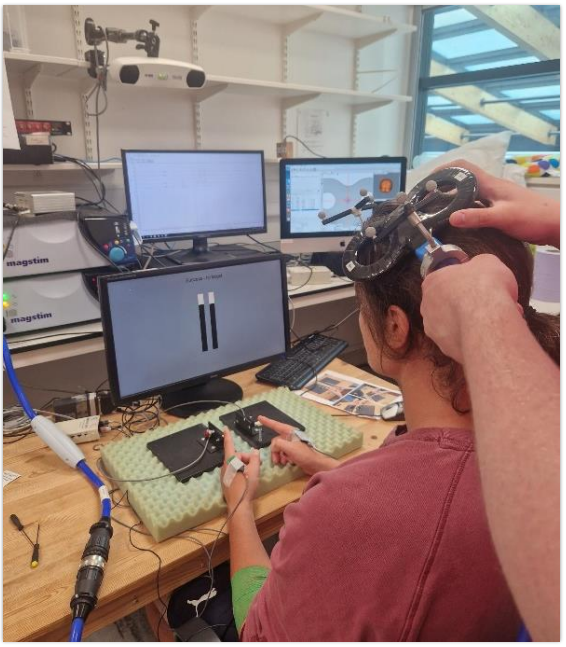
EEG set-up for session 1

A good recording of EEG data requires the electrodes in this headcap to be close to your scalp. This means that the amount of time taken to set-up the electrodes will vary depending on the amount and style of your hair. You will be reimbursed for this time accordingly. In rare cases, we may be unable to place the electrodes close enough to your scalp, and so we will need to stop the study. In these cases, you will be reimbursed for the time taken up to that point.

If you wear a head covering and require a female experimenter to fit the EEG headcap due to you needing to remove your head covering, please let us know.

Session 2 – TMS:

The second session will take place at the School of Sport, Exercise, and Rehabilitation Sciences, University of Birmingham. In this session, we will apply safe, non-invasive brain stimulation (TMS) when you are at rest and whilst you perform the same movement task. We use TMS to assess the strength of the connection between your brain and your muscles. This involves placing a coil in a specific position over your head, which is connected to a machine that delivers a small magnetic pulse to the nerves in the brain. The stimulation, which is not painful, produces small brief contractions in the hand and arm muscles. We measure these contractions by attaching electrodes to your hands (EMG) and the size of these contractions provides us with an indirect measure of brain activity at the time of stimulation. This technique is safe and part of standard clinical tests worldwide.



TMS set-up for session 2

More information about TMS can be found here: https://pubmed.ncbi.nlm.nih.gov/33243615/.

Questionnaires:

In both sessions, you will be asked to complete questionnaires about your experiences in daily life, impulses you experience, and thinking processes, which will require either verbal or written responses. You will be asked to complete a standard clinical questionnaire, which assesses non-movement and movement experiences of daily living and involves a movement examination (known as the Movement Disorder Society-Sponsored Revision of the Unified Parkinson's Disease Rating Scale). For this assessment, you will be asked to perform various movements, including toe-tapping, fist clenching/unclenching, and walking. Please note these questionnaires cannot be used to diagnose a condition, such as an impulse control disorder, but can be used to identify difficulty controlling impulses.

Compensation

You will receive £10 compensation per hour you spend with us along with travel reimbursement via bank transfer. Payment may take up to 6 weeks to process. We can also provide Amazon vouchers as an alternative to bank transfer.

What are the possible benefits of taking part?

In the future, this line of research has the potential to assist doctors in identifying individuals with Parkinson's disease who have a higher risk of developing impulse control problems.

What are the possible disadvantages and risks of taking part?

The assessment techniques are safe to use, non-invasive and there are no known risks from having these tests performed under strict safety guidelines. All tests will be performed within your comfort range. All electrical equipment will be subject to safety assessments.

Movement task (both sessions): You may experience mild muscle ache from the repetitive movements involved in the task, which will generally release within 3 days after the session.

EMG (both sessions): To place the EMG electrodes on your hands, the skin must first be prepared with an alcohol wipe and the electrodes will be carefully attached using tape. This can result in a mild and temporary irritation of the skin that does not require treatment. Electrical equipment for recording EMGs from muscle is electrically isolated from the mains, eliminating risk of electrocution.

EEG (session 1): There is a low chance of mild skin irritation at some contact points between the electrodes and your skin. This will be monitored during the session. Please inform the experimenter if you feel any discomfort.

TMS (session 2): Is considered a safe non-invasive technique, which will be used according to well-established international guidelines. Before undergoing TMS, you will be asked to complete a TMS safety questionnaire to ensure it is safe for you to do so. Occasionally, TMS may be associated with minor discomfort or mild headache, which invariably settle with time or common pain medication. Nevertheless, the experimenter will check that you are comfortable during the experiment. Please inform the experimenter if you feel any discomfort.

TMS can be harmful in people who have a pacemaker or metal implants in their body. Please inform the investigators if you might have any metal in your body. In rare instances, TMS has been reported to induce seizures in individuals already susceptible to seizures with a family history of epilepsy and, in extremely rare cases, in otherwise healthy individuals. Please inform the investigators if there are

cases of epilepsy in your family. Since the effects of TMS on the foetus are unknown, you are advised not to take part if you might be pregnant.

To ensure consistent placement of the TMS coil, we use a motion tracking system. To achieve this, you will be asked to wear a headband with an attached device throughout the task, which may cause some discomfort. Please let the experimenter know if the headband feels too tight.

Your right to withdraw

If you would like to take part, you will be asked to sign a consent form. Even after you have signed this consent form and agreed to join the study, you are free to withdraw from the study at any time without providing a reason and without any penalty. If you wish to stop participating, simply inform the experimenter. We need to manage your data in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we collect. If you withdraw before completion of the full study, you will be compensated for your time up to that point. If you withdraw, you can also request that we destroy any data that we collected from you. If you wish us to do this, you must make your request by email *within one week* of withdrawing from the study. Once analysis has begun, data cannot be removed, and data already collected with consent will be retained and used in the study.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Confidentiality and data security

We will need to use information from you for this research project. This information will include your name, contact details, demographic information and information collected during the screening process and study sessions. People will use this information to do the research to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What will happen to the results?

The results of this study will be analysed by the research team and included in student dissertations, presented in academic talks, and published in academic journals. Data will always be anonymous. Fully anonymised data may be made publicly available online at the time of publishing of any academic papers that include the results from this study. Importantly, this data will contain no personal identifiers, and cannot be linked to you. Further details regarding the purpose of this research will be provided after completion of the study.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to dataprotection@contacts.bham.ac.uk

Who has reviewed the study?

All research studies are checked by an ethics committee to ensure the research is conducted safely and to the best standards. This research has been reviewed by, and received favourable opinion, through the NHS Research Ethics Committee, Rec Ref South-East Scotland REC 02.

The study is sponsored and insured by the University of Birmingham and is being completed as part of a PhD qualification.

Funding

This research project is funded by the Humane Research Trust.

Contact details

If you are unsure about this study and would like to consider further before you make your decision, please take your time to do so. You may ask for further information by contacting a member of the team. Their contact details are provided on the top right corner of the first page. Alternatively, if you would prefer to contact an independent person who is not involved in the study to seek advice on the involved procedures, please contact Dr Ned Jenkinson (tel. +441214147239, email: n.jenkinson@bham.ac.uk).

For any complaints about the study, please contact Dr Birgit Whitman, Head of Research Governance and Integrity (tel. 0121 415 8011, email: b.whitman@bham.ac.uk).