UNIVERSITY OF BIRMINGHAM | CHBH CENTRE FOR HUMAN BRAIN HEALTH

Dynamics of motivated decision-making

Information sheet for behavioural study

Please read this information carefully before deciding whether you wish to take part in the study. You may wish to discuss with your friends or family members before making a decision. If you have any further questions please contact Jamie Talbot at jxt289@student.bham.ac.uk or Matthew Apps at m.a.j.apps@bham.ac.uk. If you have any medical/ other problems which make it difficult for you to read this information, please contact Jamie Talbot who may adapt the format of this information sheet or address any problems.

Background

You are being invited to take part in a research study being conducted in the Department of Psychology at the University of Birmingham because you have previously been diagnosed with Parkinson's disease. This research work, being led by Professor Matthew Broome, a clinical psychiatrist and mental health researcher, and Dr Matthew Apps, a researcher in motivation neuroscience, looks at decision-making in those with or at higher risk of experiencing motivation problems, including individuals with Parkinson's disease and individuals with or at high risk of developing psychosis. An additional aim of the study is to examine specific effects of dopamine on motivation symptoms. Our hope is that the study will enable us to better understand these problems and thus find appropriate ways to treat them.

What will happen if you decide(s) to participate?

Where will the research take place?

The research will take place at the Centre for Human Brain Health, School of Psychology, University of Birmingham, Birmingham B15 2TT.

Who will be involved in collecting the data?

Members of the research team including Dr Jamie Talbot, a medical doctor completing a doctoral research project as part of this study.

How long will participation in the study take?

The study will consist of either one or two in-person sessions which will each take between 2 and 2.5 hours. If you usually take medication for

Parkinson's disease and agree to participate in two sessions, we will ask you to delay your usual dopaminergic medication (such as Sinemet or Madopar) on the morning of one of the testing days, in order to examine specific effects of dopamine supplementation on decision-making.

What will you be required to do during the study?

You will be asked to complete several self-report rating questionnaires, which assess things like motivation, cognitive functions, mood and fatigue. Your symptoms of Parkinson's disease will also be assessed in the form of a questionnaire and short clinical examination. These assessments should not take more than 30-40 minutes to complete. They will be recorded electronically and/or on paper.

You will also complete a computer-based decision-making task. For this, you will make decisions which either result in physical effort or winning credits. For the physical effort choices, your decisions will determine the force at which you must squeeze a handheld force meter. Performance on both tasks will determine an additional payment at the end of the experiment.

Will I be paid compensation for my time?

You will be paid a fixed rate of £25 for your participation in a study session. You will also receive an additional payment depending on your performance in the task, up to a maximum of £10, and can therefore hope to earn a maximum of £35 for a single testing session. If you travel to the Centre for Human Brain Health to complete the assessments, we will compensate for reasonable travel costs (the researcher will get in touch prior to testing sessions to confirm transport arrangements) and can arrange for free parking in front of the School of Psychology during your visit.

Will assessments be recorded?

The computer-based study collects electronic data about things like which buttons are pressed but make no use of video or audio recording.

Are there any risks that individuals taking part in the study might face?

As part of the experiment, you will be asked to squeeze a handheld device with varying amounts of force. Although the requested levels of force should be achievable, the squeezing is intended to feel effortful and therefore may be uncomfortable at times. The experiment has been designed to include frequent rest blocks in order to minimise discomfort. Given that squeezing may aggravate conditions such as carpal tunnel

syndrome, wrist or finger injuries, or arthritis of the small joints, it is important to inform the experimenter of any relevant conditions prior to the experiment. If you experience significant discomfort, the experimenter will terminate the experiment.

The questionnaires ask about things like motivation and the impact of your symptoms on activities of daily life. Although none of the questionnaires enquire about highly sensitive information about your personal life, it is possible you may find some of the questions upsetting or distressing. You have no obligation to complete the questionnaires if you do not feel comfortable and are encouraged to discuss with the researcher if you do not wish to continue.

If you agree to attend two testing sessions, you will be asked to delay your usual medication for Parkinson's disease on the morning of one of one of the sessions. Witholding this medication is likely to exacerbate your Parkinson's symptoms, increasing the risk of things like trips and falls. You may find that delaying medication is not feasible due to your symptoms, in which case we would be happy for you to participate in only one session. If, after reflecting on your individual symptoms and circumstances, you feel you would feel safe and happy to delay your usual dopamine-based medication for one of the sessions, we will be in touch to ensure that this can be done safely and arrange any necessary provisions including travel, mobility aids and any other suitable provisions for your safety and comfort. Delaying your medication and taking part in a second session is completely optional.

What are the potential benefits for participants from taking part?

You will not benefit directly from participating in this study, although we hope the results will contribute to our understanding of the cognitive processes influencing motivation in Parkinson's disease, and therefore improve our ability to help patients in the future. Participation in the study, or your decision not to participate, will in no way affect your usual clinical care.

Please remember that we are a research facility rather than a clinic. All assessments will be completed for research purposes and therefore are not to be interpreted as part of a clinical evaluation. If you have any concerns regarding your performance, other services that may be able to offer you support are available, including clinical and educational assessment and treatment services through the National Health Service (NHS).

Where will data be stored?

We will need to use information from you for this research project.

This information will include your initials, name, contact details and information from the questionnaires and experiment sessions. People will

use this information to do the research or 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.

Electronic data will be stored in password-protected files.Any paper records will be stored in locked filing cabinets at the University of Birmingham. All information gathered about you will be stored separately from any information that would allow someone to identify who you are (this is known as personal identifying information, e.g. your full names, your address, your contact details). Your personal identifying information will be stored in a separate, password-encrypted data file held at the University of Birmingham and only members of our research team will have access to it. We will only be able to trace information we have collected about you back to you using a special reference number linked to your personal details in this datafile. Personal identifying information will be treated as strictly confidential and handled in accordance with the provisions of the General Data Protection Regulation 2018.

If you decide to participate, what will happen after that participation?

You may, if you wish, receive an individual feedback report describing the results of the behavioural, cognitive and questionnaire assessments that were carried out during the study.

All participants (including carers/associates) will be invited to join a Patient Public Involvement (PPI) group. Public participation is increasingly viewed as essential to ensuring research is inclusive, values all contributions, ensures people have a meaningful say in what happens and influences outcomes (https://www.ukri.org/news/shared-commitment-to-improve-public-involvement-in-research/). As researchers, we will aim to share our research findings, including dissemination of any published reports, to the PPI group, and encourage feedback on any aspects of the study aims, design, conduct or results.

We may contact you at some point after the study session to invite you to participate in a more in-depth clinical interview about your personal experience of motivation. However there is no obligation to take part in this interview. Further information will be provided at the time.

The researchers will aim to publish the findings from the study in scientific journals and present the results at academic conferences. We will aim to

submit manuscripts for peer review within one year of the end of the study period.

What will happen to the data afterwards?

At the end of the study, your personal details will be destroyed. For example, your behavioural or questionnaire data would not be linked to any document containing personal details like your name, age or contact details. Data would contain information relating to things such as gender, age, date of test, and handedness information, although this information could not be used to identify someone. We would retain the research data for 10 years, in line with University of Birmingham policy. After this your data will be destroyed.

Confidentiality

The confidentiality of participants will be ensured. If published, information on the participant will be presented without reference to their name or any other identifying information.

Consent

After you have read all of the information and have received appropriate responses to any questions that you may have about the study, you may decide that you wish to participate in the research. In this case, you will then need to fill out a short screening questionnaire to ensure that you meet the eligibility criteria for the study. If you meet the criteria for eligibility, a researcher will be in touch to arrange an in-person study session. If you do not meet the criteria, your responses to screening questions and any personal data will be deleted. We will complete the screening questionnaire with you over the phone or we will send you an online link.

If invited to attend an in-person testing session, you will be asked at the start of the session to provide written consent to participate in the research study by signing a consent form. For full information on the consent you will be giving, see each point on our consent form. We need to receive consent from you in order for you to participate. Your choice about whether or not to participate will not in any way affect your usual treatment.

Withdrawal

Even after consent has been granted, you can request to be withdrawn from the study without giving a reason. You will have one month after participation to make this request. You will be able to decide if you would like your research data to be destroyed or retained by the project team. Your withdrawal will not restrict access to other services and will not affect the right to treatment.

We need to manage your records 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 hold about you.

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

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Please contact Jamie Talbot at jxt289@student.bham.ac.uk or Matthew Apps at m.a.j.apps@bham.ac.uk in the first instance. If you remain unhappy and wish to complain formally, you can contact: Prof. Ed Wilding; Head of School; School of Psychology, University of Birmingham, Birmingham, B15 2TT, by email: hos.psychology@contacts.bham.ac.uk or by phone on 0121 414 4931.

Review

The study is sponsored and insured by the University of Birmingham and is funded by the Wellcome Trust. The study has been approved by London - South East Research Ethics Committee.

Further information

If you would like any more information about the study please contact Jamie Talbot at jxt289@student.bham.ac.uk or Dr Matthew Apps at m.a.j.apps@bham.ac.uk or write to them at the School of Psychology, University of Birmingham, Edgbaston, Birmingham, B15 2TT.