



Participant Information Sheet Participant version

Non-Interventional Study - Adult providing own consent

Flinders University

Title	<i>Mood and motivation in Parkinson's disease</i>
Short Title	<i>Assessment of mood and motivation in PD</i>
Protocol Number	<i>2022/HRE00143</i>
Coordinating Principal Investigator/ Principal Investigator	<i>Stephanie Wong</i>
Associate Investigator(s)	<i>Caitlin Christian, Elli Kolovos</i>
Location	<i>Flinders University</i>

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, "*Mood and motivation in Parkinson's disease (PD)*". This study aims to understand emotional changes associated with Parkinson's Disease, such as depression, apathy (loss of motivation) and anhedonia (loss of pleasure). We aim to discover how often depression, apathy and anhedonia occur in people with Parkinson's Disease compared to people without Parkinson's Disease, and to determine how best to identify these emotional changes in the clinic.

If you do *not* have a diagnosis of Parkinson's Disease, you have been invited to participate in the comparison/control group.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the tests and research that are described
- Consent to the use of your personal and health information as described.

You may download a copy of this Participant Information Sheet to keep.

2 What is the purpose of this research?

Physical symptoms, such as tremor and slow, rigid movements, are the most common observable symptoms of Parkinson's Disease. However, emotional changes can also occur. People with Parkinson's Disease may experience changes in mood, motivation and the ability to experience pleasure. These changes are described as symptoms of depression, apathy and anhedonia. Because these symptoms often co-occur and share common features, they are often mistaken for one another, or not recognised at all. This can lead to lower quality of life and wellbeing, as well as higher carer burnout.

This project aims to understand experiences of depression, apathy and anhedonia in people with Parkinson's Disease and to improve the way these symptoms are identified in clinical settings.

In this project, we will collect questionnaire responses from 2 groups of individuals: those with a diagnosis of Parkinson's Disease and those without a diagnosis of Parkinson's Disease. Questionnaire responses will be compared between the 2 groups to determine whether symptoms of depression, apathy and anhedonia are different in Parkinson's Disease.

For people with Parkinson's Disease, we also ask that a Support person(e.g., a spouse, partner, family member or friend) complete some questionnaires on their behalf. In some research and clinical settings, support people or carers are asked to respond on behalf of the person they are caring for. This can sometimes be difficult, as the questions can be quite personal. By asking support people to complete the same questionnaires, we aim to compare the responses and determine the best way to identify changes in symptoms of depression, apathy and anhedonia.

Results from this study will improve current understanding and assessment of emotional Parkinson's Disease symptoms such as depression, apathy and anhedonia. This may contribute to improvements in the way these symptoms are identified in the clinic, and lead to future development of better treatments. We hope that this will help improve quality of life and wellbeing for people with Parkinson's Disease, and help reduce carer burnout.

This research was part of a Psychology Honours thesis, which is now completed. is not funded by any grant or sponsorship. We are continuing the research until December 2023 to ensure we meet the research aims.

3 What does participation in this research involve?

If you choose to participate in this study, you will be asked to sign the consent form online, provide your email address and indicate whether you have been diagnosed with Parkinson's Disease. You will then be emailed a personalised weblink to access and begin the study.

The study will involve answering questions on a set of online questionnaires.

First, you will be asked to provide brief details about your personal and medical history (e.g., age, years of education, languages spoken, diagnosis of Parkinson's Disease and/or other neurological or mental health conditions) and your current experience of symptoms of Parkinson's Disease (if diagnosed).

Second, you will be asked questions about your current experiences of symptoms of depression, apathy and anhedonia.

Finally, if you are participating in this study as a person with Parkinson's Disease, we will ask your support person to complete a set of questionnaires about your experiences of apathy and anhedonia.

As the study is completed online from your home, you may pause at any time and resume the study when you are comfortable doing so, using the personalised link in your email. We ask that you complete the questionnaires within 2 weeks of beginning the study. We will send a reminder email after 1 week if it has not yet been completed.

Your participation in this study, from reading this *Participant Information and Consent Form* to completing the questionnaires should take approximately 30-40 minutes in total.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study investigators or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid.

4 What do I have to do?

To participate in this study, you will be asked to sign the online *Consent Form*, provide your email address and indicate whether you have been diagnosed with Parkinson's Disease. You will then be emailed a personalised link to complete a set of questionnaires (as described above).

Each of the questionnaires contain less than 20 questions. You will be asked to provide answers such as 'yes' or 'no', or rate your agreement with statements on a scale provided. There are no requirements for lifestyle changes or physical activities while participating in this study.

5 Other relevant information about the research project

Approximately 120 total people will be taking part in this study, including people with and without a diagnosis of Parkinson's Disease.

This project is run solely by researchers at Flinders University. It is linked to future research projects on mood and motivation in Parkinson's Disease.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this *Participant Information and Consent Form* to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Flinders University.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any direct benefits from this research, however possible benefits may include contributing to knowledge and awareness about depression, apathy and anhedonia in Parkinson's Disease.

There will be no clear immediate benefit to you from your participation in this research.

8 What are the possible risks and disadvantages of taking part?

There is a small risk of experiencing mild fatigue while completing the online questionnaires. If you are worried about fatigue, please feel free to take a break while completing the questionnaires at your own pace. You have up to 2 weeks to complete all the questionnaires. The total time to complete all the questionnaires is around 30–40 minutes.

There is also a small risk of distress when answering the study questionnaires. If you become upset or distressed as a result of your participation in the research, we recommend you seek support from the services listed in Section 9 below.

There may be risks that the researchers do not expect or do not know about and that may be serious. Tell your study investigator immediately about any new or unusual symptoms by email or phone (stephanie.wong@flinders.edu.au, (08) 7221 8448).

9 What if new information arises during this research project?

Sometimes during the course of a research project, incidental findings apart from those connected to the research question arise. In this study, your questionnaire response may indicate elevated symptoms of depression. We will not be able to inform participants of their individual outcomes as identifying information will be removed from the data prior to analysis. If you feel the need to speak to someone, please contact your GP or the following support services:

- Parkinson's Australia Support Line: 1800 644 189
- Beyond Blue: 1300 22 4636 or <https://www.beyondblue.org.au/support-service/chat>
- Lifeline: 13 11 14

10 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may continue taking any treatments you are currently accessing. You are not required to change your lifestyle behaviours in any way.

11 What if I withdraw from this research project?

If at any point during the study, you wish to withdraw from this research project, you can do so through the following options:

1. By emailing the Principal Investigator (stephanie.wong@flinders.edu.au) or
2. By completing the Withdrawal of Consent form (a link to this form will be provided in the email containing your personalised link to the study) or
3. By simply not completing the online questionnaires within the expected time frame of 2 weeks (a reminder email will be sent 1 week after you begin). If you do not complete all

the questions, we will assume that you are no longer interested in participating and will withdraw you from the study.

If you do withdraw your consent during the research project, the study investigators will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will not form part of the research project results. If you do not want them to do this, you must tell them before you join the research project. Data collected will be kept on a secure drive at Flinders University for five years before being deleted from the drive, in accordance with South Australian record regulations.

12 Could this research project be stopped unexpectedly?

This research project will not be stopped unexpectedly as it is an online questionnaire study.

13 What happens when the research project ends?

Once you have responded to the set of online questionnaires, a page will appear to let you know that your participation in the project has been completed. On this completion page, you will be asked to indicate if you would like to know about the overall results of the project. If you indicate 'yes', you will receive an email briefly explaining the study findings and contributions to this research area upon completion of the study in December 2023.

Part 2 How is the research project being conducted?

14 What will happen to information about me?

By signing the consent form, you consent to the study investigator and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Data collected will be deidentified, with any identifiable information kept on a password protected file and folder in a secure Flinders University drive. This will only be accessible to investigators listed on this project.

Data will be kept for 5 years as per the Flinders University storage policy and will be removed from the secure drive after this time. The project does not involve establishment of a databank. Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. In any publications, results will be discussed in general terms after analysis with no identifiable information included.

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team. Please contact the research team member named at the end of this document if you would like to access the information.

Any information obtained for the purpose of this research project and for possible future research that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. If you do not consent to possible future use (with further ethics approval) of your data please tell the study investigators.

15 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

If you have any complaints please contact the investigators or complaints personnel of the Human Research Ethics Committee using the contact details below, and they will assist you in addressing the issue.

16 Who is organising and funding the research?

This research project is being conducted by Dr. Stephanie Wong.

You will not benefit financially from your involvement in this research project.

If knowledge acquired through this research leads to discoveries that are of commercial value to Flinders University or the study investigators there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

17 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Southern Adelaide Clinical Human Research Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Approval has been given by Flinders University where the research team will be based.

18 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the chief investigator on (08) 7221 8448 or any of the following people:

Clinical contact person

Name	Dr. Stephanie Wong
Position	Chief Investigator
Telephone	(08) 7221 8448
Email	stephanie.wong@flinders.edu.au

Other contacts

Name	Caitlin Christian
Position	Research Assistant

Telephone	(08) 7421 9263
Email	Caitlin.christian@flinders.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	<i>Southern Adelaide Local Health Network</i>
Position	<i>Manager, Research Governance and Ethics</i>
Telephone	<i>8204 6453</i>
Email	<i>Health.SALHNOfficeforResearch@sa.gov.au</i>

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	<i>Southern Adelaide Clinical</i>
HREC Executive Officer	<i>Executive Officer</i>
Telephone	<i>8204 6453</i>
Email	<i>Health.SALHNOfficeforResearch@sa.gov.au</i>

Local HREC Office contact (Single Site -Research Governance Officer)

Name	<i>Southern Adelaide Local Health Network</i>
Position	<i>Research Governance Officer</i>
Telephone	<i>8204 6453</i>
Email	<i>Health.SALHNOfficeforResearch@sa.gov.au</i>

