

**Title of Study: The Exploring Emotion Regulation Changes in
Parkinson's disease**

PARTICIPANT INFORMATION SHEET

We would be grateful if you could assist us by participating in our online study which has been designed to explore changes in emotion regulation in Parkinson's disease (PD).

Please take some time to read the information sheet below. If you have any further questions, please do not hesitate to contact the researchers using the details provided. Thank you!

What is the purpose of the study?

Changes in emotion regulation strategies has scarcely been evaluated in individuals with Parkinson's disease (PD) and establishing the relationship between cognitive decline in PD is of great importance in determining potential intervention and therapeutic targets.

Alexithymia, defined as having difficulty describing and communicating one's feelings is prevalent in PD and is often associated with symptoms of depression, anxiety, apathy, and impulsivity. Alexithymia is also known to have consequences on quality of life and one's ability to regulate their emotions using strategies such as positively reinterpreting a negative situation and putting things into perspective.

Emotion regulation can be harder to employ for individuals living with conditions, such as PD, that affect executive functions which refers to specific mental abilities such as switching between two activities, actively ignoring irrelevant information, and actively updating the information you keep in mind. These functions have been shown to be crucial for coping with the mental challenges in everyday situations and seem to help with emotion regulation.

In this online study, we aim to evaluate whether is a relationship between executive functioning and cognitive (i.e., positively reinterpreting) and behavioural (i.e., avoidance) emotion regulation strategy use in individuals with PD. Furthermore, we aim to establish the effect of the relationship between executive functions and emotion regulation strategy use on mental wellbeing in PD.

Eligibility Criteria

We are recruiting individuals diagnosed with Parkinson's disease.

To be eligible to participate in this study, you must meet the following criteria:

- 18 years or older
- English Speakers
- Have access to a computer or laptop.
- Have normal or correct-to-normal vision and hearing

The exclusion criteria for the study include:

- A history of a serious head injury
- A diagnosis of a neurological disease other than Parkinson's disease
- A history of a severe mental health condition requiring in-patient treatment

What would taking part involve?

You will first be asked to complete a consent form, demographics questionnaire and an informed consent questionnaire.

You will then be invited to schedule a video call via Microsoft Teams, during which you will complete a short cognitive screening and a questionnaire relating to motor and non-motor aspects of daily living. Following this, you will be asked to complete self-report questionnaires relating to mental wellbeing, health-related quality of life, alexithymia, cognitive and behavioural emotion regulation strategy use, apathy, anxiety, and depression. You will also complete three tasks measuring executive functioning.

The tasks and questionnaires will be completed independently (i.e., at home) on a computer or laptop and takes approximately one hour and thirty minutes.

The primary researcher will remain on the video call with you during completion of the questionnaires and tasks should you require assistance or have any questions.

What are the possible disadvantages or risks of taking part?

We foresee few risks during the experiment, however you will be asked to complete questionnaires designed to measure symptoms of cognitive impairment, anxiety and depression. If the information you share with us during the research, such as your responses on the screening questionnaire, raises a significant concern about your mental health, we will attempt to contact you using the contact details you have provided in the Consent Form to discuss with you whether you would consider seeking help and advice from a clinically qualified professional including your General Practitioner.

Do I have to take part?

Taking part in this study is completely voluntary; you may withdraw at any time without having to give a reason.

Expenses and/or payments

There is no payment for taking part. You will not incur any costs by taking part.

As an incentive for your taking part, a donation per participant who completes the study will be made the charity Carer's UK (<https://www.carersuk.org>).

Will my data be confidential?

Your data will be kept confidential with only a coded participant ID number identifying it.

Data collected from this study will be preserved in anonymised form and may be made available via a public data repository. No confidential or personally identifiable information will be shared with third parties or deposited publicly.

How will my data be stored?

The data collected for this study will be stored securely and privately on a password-protected University of Reading online server (OneDrive), based in the UK. The files will be encrypted, that is no one other than the Research Team will be able to access them, and your information will be managed in line with General Data Protection Regulation and all applicable data protection laws and will be deleted when no longer needed.

The organisation responsible for protection of your personal information is the University of Reading (the Data Controller). Queries regarding data protection and your rights should be directed to the University Data Protection Officer at imps@reading.ac.uk, or in writing to: University of Reading, Information Management & Policy Services, Whiteknights House, Pepper Lane, Whiteknights, Reading , RG6 6UR, UK.

The University of Reading collects, analyses, uses, shares and retains personal data for the purposes of research in the public interest. Under data protection law we are required to inform you that this use of the personal data we may hold about you is on the lawful basis of being a public task in the public interest and where it is necessary for scientific or historical research purposes. If you withdraw from a research study, which processes your personal data, dependant on the stage of withdrawal, we may still rely on this lawful basis to continue using your data if your withdrawal would be of significant detriment to the research study aims. We will always have in place appropriate safeguards to protect your personal data.

If we have included any additional requests for use of your data, for example adding you to a registration list for the purposes of inviting you to take part in future studies, this will be done only with your consent where you have provided it to us and should you wish to be removed from the register at a later date, you should contact Caroline Seton via c.seton@pgr.reading.ac.uk.

You have certain rights under data protection law which are:

- Withdraw your consent, for example if you opted in to be added to a participant register
- Access your personal data or ask for a copy
- Rectify inaccuracies in personal data that we hold about you
- Be forgotten, that is your details to be removed from systems that we use to process your personal data
- Restrict uses of your data
- Object to uses of your data, for example retention after you have withdrawn from a study

Some restrictions apply to the above rights where data is collected and used for research purposes.

You can find out more about your rights on the website of the Information Commissioners Office (ICO) at <https://ico.org.uk>

You also have a right to complain the ICO if you are unhappy with how your data has been handled. Please contact the University Data Protection Officer in the first instance.

What will happen to the results?

The results will be summarised and reported in a doctoral thesis as part of the PhD Programme at the University of Reading (UK). Furthermore, the results are expected to be submitted for publication in academic or professional journals, and may be shared as part of lay reports, web pages, press releases, conferences, and training material.

This application has been reviewed by the University Research Ethics Committee and has been given a favourable ethical opinion for conduct (23/26).

If you have any questions or concerns about the research, please feel free to contact the research team (details below).

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