

**Title of Study: Emotion Regulation Tendencies and Well-Being in
Parkinson's Disease: A New Perspective**

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 tendencies and well-being 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?

The ability to regulate emotions is crucial for mental health yet is underexplored in individuals with Parkinson's disease (PD). Symptoms like depression, anxiety, apathy, and alexithymia (referring to difficulty in describing and communicating one's feelings) can all impact mental well-being and quality of life in both clinical and non-clinical populations. Understanding the relationship between individuals' tendencies to use certain strategies to regulate emotions, such as reappraisal (reinterpreting a negative situation) or distraction (shifting focus away from the negative situation), and beliefs about one's ability to manage emotions can provide insights into their impact on mental well-being, will facilitate the identification of potential therapeutic targets.

In this online study, we aim to assess whether individuals with Parkinson's Disease (PD) differ in their tendency to select reappraisal or distraction in an emotion regulation task compared to a group of age-matched healthy individuals. Additionally, we intend to investigate whether there is a relationship between the choice of regulation strategy and emotion regulation self-efficacy, how regulatory tendencies and self-efficacy are related to mental well-being indicators and cognitive functioning, as well as how these mental well-being indicators are related to cognitive functioning.

Eligibility Criteria

We are recruiting individuals diagnosed with Parkinson's disease as well as age- and gender-matched controls (older adults) who do not have a diagnosis of 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?

1. You will first be asked to complete a consent form, demographics questionnaire and an informed consent questionnaire.
2. You will then be invited to schedule an online session with the primary researcher which takes place over video call via Microsoft Teams, during which you will complete:
 - A short cognitive screening assessment
 - A questionnaire relating to motor and non-motor aspects of daily living.
 - Three cognitive tasks
 - An emotion regulation task, choosing between reappraisal and distraction to assess your tendency to select each strategy in response to emotionally evocative images high- and low-intensity.

The online session takes approximately **1 hour**, and you welcome to take breaks as needed.

3. You will be asked to complete a set of self-report questionnaires on cognitive functioning in daily life, emotion regulation self-efficacy and tendency, mental well-being, health-related quality of life, alexithymia, apathy, anxiety, and depression.

The self-report questionnaires should be completed within one week of your online session and takes approximately **35 minutes**.

This study will be conducted remotely (i.e., you will participate from your own home) on a computer or laptop.

What are the possible disadvantages or risks of taking part?

We foresee few risks during the experiment, but we will be measuring your reactions when you are presented with emotionally evocative images. Individuals differ in their reaction to such stimuli, and some may find some of these shocking and disturbing. These images contain scenes of human poverty, animal corpses, drug use, illness, injury/mutilation, violence, and death. These images can be more graphic than scenes depicted on G-rated television programmes. But they are not more graphic than those observed in some types of photojournalism or in PG15-rated videos/movies; they are comparable to scenes that are found via internet search. While the purpose of showing you these images is to induce negative feelings during the experiment, emotional reactions to these stimuli may be prolonged or come after you have participated in the study. It is not recommended that you participate if you think you are particularly sensitive to these kinds of materials.

If you decide to take part, you will complete a practice emotion regulation task during which a few representative examples of the images have been included, allowing you the opportunity to decide whether you wish to proceed with participating in the study. You are free to withdraw your participation at that point if you find that this is not the right study for you. In addition, please remember that you are free to terminate your participation at any time and for any reason. If at any point, you begin to feel distressed by the images, please let the researcher know.

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 questionnaires, 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 or we may suggest you seek help from a mental health charity or other relevant mental health services. By participating in this study, you consent to being contacted by the researcher should your scores indicate clinically significant levels of symptomatology. This contact is intended to ensure you are aware of potential mental health concerns and to encourage you to seek appropriate help if needed.

Do I have to take part?

Taking part in this study is completely voluntary.

If you choose to withdraw at any point, you can do so without providing a reason and without facing any negative consequences. To withdraw, please inform the primary researcher immediately. The researcher will provide immediate support and resources, including a debriefing session during which you will be provided with information about available mental health services. You will also have the option to engage in a soothing activity to help alleviate any negative emotions you may experience during the study. Your well-being is our priority, and we are here to support you throughout the study.

Expenses and/or payments

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

Will my data be confidential?

Your data will be kept confidential with only a coded participant ID number identifying it for the duration of the study.

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?

Any personal 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, or using your anonymised data from a previous study for exploratory analysis, this will be done only with your consent where you have provided it to us. Should you wish to be removed from the register or withdraw your consent for the use of your data from the prior study 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 (24/19).

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

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