

**Title of Study: The Effects of Computerised Cognitive Training of
Executive Functioning on Emotion Regulation**

PARTICIPANT INFORMATION SHEET

We would be grateful if you could assist us by participating in our online study which has been designed to measure the effects of a computerised cognitive training intervention targeting executive functioning on emotion regulation ability. 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?

Executive functions refer to specific mental abilities such as switching between two activities, actively ignoring irrelevant information, and actively updating the information you keep in mind, such as a shopping list. When executive functions are impaired, as is often the case for individuals diagnosed with Parkinson's Disease (PD), one may find it difficult to store, manipulate and update information; collectively known as working memory. These functions have been shown to be crucial for coping with the mental challenges in everyday situations and seem to help with emotion regulation.

More specifically, executive functions such as working memory appear to help with effective emotion regulation strategies, such as reappraisal. Reappraisal refers to the process whereby the individual interprets a situation in a different way so that the (negative) emotion is either made stronger or reduced. Utilising a strategy such as reappraisal in which the evaluation of a situation leading to stress is reduced is known to have beneficial effects on well-being and mental health. Emotion regulation can be harder to employ for individuals living with conditions that affect executive functions, with consequences for PD progression.

The use of a computerised cognitive training (CCT) intervention to train working memory presents an interesting and novel approach which targets both executive functioning and emotion regulation. Cognitive training using guided practice on a set of tasks related to specific brain functions such as memory or attention, can improve cognitive (or mental) abilities in much the same way that physical training improves physical abilities. There is some initial evidence suggesting that such training may help cognition in individuals with PD, but this requires further research. The extent to which such an intervention affects emotion regulation is not yet known.

Eligibility Criteria

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

- Between the ages of 45 years to 75 years old
- Have a diagnosis of Parkinson's disease
- Have access to a computer or laptop with a speaker
- 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 diagnosis of a mental health condition
- Undergone deep-brain stimulation
- A Geriatric Depression Scale score of ≥ 11

What would taking part involve?

This research study consists of three phases. In the first phase, you will complete pre-training assessments to establish baseline performance, which include an emotion regulation questionnaire, a set executive functioning tasks, and a reappraisal task. The pre-training assessment approximately 45 minutes and you are welcome to take breaks.

In the second phase, you will complete the computerised cognitive training intervention, consisting of ten training sessions over the course of two weeks. You may complete one training session per day, each of which is likely to take approximately 20 minutes. You will be randomly allocated to complete either an experimental or control intervention.

In the third phase, you will complete post-training assessments one month and two months intervals after completing the cognitive training intervention. This will include the same baseline measures as described above in phase one and will take approximately 45 minutes. All phases of the experiment will be completed independently (i.e., at your own time at home) using a laptop or desktop computer.

What are the possible disadvantages or risks of taking part?

We foresee few risks during the experiment, but you will be 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 car accidents, animal corpses, human poverty, medical procedures (dentistry), drug use, illness, death, and gun violence. 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.

You will complete a practice task during which three 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 will be provided with an "Early Exit" option throughout the study and are free to terminate your participation at any time. Emotional reactions to these stimuli may be prolonged or come after they have participated in the study. It is not recommended that volunteers participate if they think they are particularly sensitive to these kinds of materials.

Prior to starting the studying, you will be asked some screening questions. It is possible that based on this information, you will not be eligible to continue with the study. 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.

Will my data be confidential?

Your data will be kept confidential with only a randomly generated PublicID identifying it.

Data collected from this study will be preserved in pseudonymised form and may be made available online in accordance with RCUK and EU Open Data policy as ‘safeguarded’ data. These data would only be available and shared in confidence to registered researchers.

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 (GDPR, 2018), 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.

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

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