

# The effects of brain training on how persons with Parkinson's disease think and feel

<b>Submission date</b> 14/11/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/11/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/07/2024	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

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.

### Who can participate?

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

What does the study 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 2-weeks, 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.

For more information please see the study advertisement on Parkinson's UK: <https://www.parkinsons.org.uk/research/can-brain-training-affect-how-you-feel-and-think>

Where is the study run from?  
University of Reading (UK)

When is the study starting and how long is it expected to run for?  
February 2022 to July 2024

Who is funding the study?  
The study is self-funded and will form part of a doctoral degree in Psychology.

Who is the main contact for the study?  
Caroline Seton  
[c.seton@pgr.reading.ac.uk](mailto:c.seton@pgr.reading.ac.uk)

### **Study website**

<https://www.parkinsons.org.uk/research/can-brain-training-affect-how-you-feel-and-think>

## **Contact information**

### **Type(s)**

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

The effects of computerised cognitive training of executive functioning on emotion regulation in Parkinson's Disease

### Study objectives

1. Supported by the findings of Peckham and Johnson (2018) who report that scores on the reappraisal subscale of the ERQ (Gross & John, 2003) significantly increased from pre-training to follow-up in a study utilising the adaptive PASAT as a working memory training (WMT) intervention, it is hypothesised that ERQ reappraisal sub-scale score of the experimental group will be significantly better than the control group post-training. Specificity of this predicted effect will be assessed by comparing any changes from pre-training to follow-up in the ERQ expression suppression subscale.
2. Is it hypothesised that reappraisal ability metrics derived from the task of the experimental group will be significantly better than the control group post-training, as supported by findings suggesting that WMT was associated with improvements in reappraisal (Peckham & Johnson, 2018) and positive emotion regulation (Schweizer et al., 2017).
3. In a study evaluating the effects of WMT in PD patients, Fellman et al. (2018) provide evidence for near transfer effects to structurally similar untrained WM tasks. Similarly, Peckham and Johnson (2018) found Digit Span improvements following WMT using the aPASAT. Therefore, it is hypothesised that performance on near-transfer task (non-adaptive PASAT) and far-transfer task (Digit Span) of the experimental group will be significantly better than the control group post-training.
4. Evidence from WMT studies using the aPASAT (Peckham & Johnson, 2018) and adaptive dual n-back task (Course-Choi et al., 2017) postulate that participants showed improved post-training accuracy on the antisaccade task, which was used as a far transfer measure of response inhibition. It is hypothesised that performance on the Go/No-Go task (measuring Inhibition) of the experimental group will be significantly better than the control group post-training.
5. It is hypothesised that at least one of the cognitive variables in which change in performance as a function of the intervention as described above will predict reappraisal ability. Toh and Yang (2021) argues that performance on the operation-span task, which is an index of working

memory ability, and inhibition as measured by the Go/No-Go task have been found to be associated with reappraisal ability. Of note, scores on the Colour-Shape task measuring set-shifting abilities, was found to be associated with reappraisal frequency, but not reappraisal ability (Toh & Yang, 2021).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 02/08/2022, University of Reading Ethics Committee (Whiteknights, Reading, Berkshire, RG6 6AH, UK; +44 (0) 118 378 7119; urec@reading.ac.uk), ref: UREC 22/08

### **Study design**

Quasi-experimental study design (randomized)

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Internet/virtual

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet.

### **Health condition(s) or problem(s) studied**

Cognitive training of executive functioning on emotion regulation in Parkinson's Disease

### **Interventions**

All participants' data will be collected via Gorilla Software ([www.gorilla.sc](http://www.gorilla.sc)).

Participants will complete a demographics questionnaire and screening measure (Geriatric Depression Scale) and an adapted version of the Older Adults' Capacity to Consent to Research (OACCR), from which their eligibility will be determined.

Participants will complete baseline assessments which will take approximately 45 minutes.

After completion of baseline measures (includes an emotion regulation questionnaire, a set of executive functioning measures, and a reappraisal task), participants will be invited to the computerised cognitive training intervention, which entails completing ten online training sessions (limited to a maximum of one session per day) over a period of two weeks.

Participants will be randomly allocated by Gorilla software to either the experimental group to engage in the working memory CCT intervention using the adaptive Paced Auditory Serial Addition Task or the control group to engage in the active control training intervention using an adapted Visual Search Task.

Post-training assessments at 2-weeks, 1-month and 2-month intervals will be completed post-intervention and will include the same baseline measures.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Measured at 2-week, 1-month and 2-month follow up:

1. Scores on the Emotion Regulation Questionnaire (Gross & John, 2003); measuring general reappraisal ability and commonly employed strategies.
2. The Positive and Negative Affect Scale (PANAS; Watson, Clark, & Tellegen, 1988); a 20-item self-report mood scale, with 10 items measuring positive emotions and 10 items assessing negative emotions.
3. The Paced Auditory Serial Attention Task (PASAT; Gronwall, 1977); measuring working memory and near-transfer effects of the intervention.
4. The Digit Span Task (Wechsler et al., 2008); measuring working memory and far-transfer effects of the intervention.
5. The Colour-Shape Task (Miyake, Emerson, Padilla, & Ahn, 2004); measuring set-shifting.
6. The Go/No-Go task (Rush, Barch, & Braver, 2006); measuring response inhibition.

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

01/02/2022

### **Completion date**

15/07/2024

## **Eligibility**

### **Key inclusion criteria**

1. Individuals diagnosed with idiopathic Parkinson's Disease.
2. Approximately aged 45 years to 75 years.
3. Normal or corrected-to-normal vision and hearing.
4. Have access to a computer or laptop with a speaker.
5. English Speaker.

### **Participant type(s)**

Patient

### **Age group**

Senior

### **Lower age limit**

45 Years

**Upper age limit**

75 Years

**Sex**

Both

**Target number of participants**

74

**Total final enrolment**

66

**Key exclusion criteria**

1. Neurological disease (other than PD).
2. A diagnosis of a mental health condition.
3. A history of serious head injury.
4. Patients with deep brain stimulation.
5. A Geriatric Depression Scale score indicating clinical levels of depression.

**Date of first enrolment**

02/08/2022

**Date of final enrolment**

04/06/2024

## **Locations**

**Countries of recruitment**

England

Northern Ireland

Scotland

United Kingdom

Wales

**Study participating centre**

**This is an online study using remote participation from home**

School of Psychology University of Reading

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# Sponsor information

## Organisation

University of Reading

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## Sponsor type

University/education

## Website

<http://www.reading.ac.uk/>

## ROR

<https://ror.org/05v62cm79>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

01/09/2025

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be published as a supplement to the results publication.



## IPD sharing plan summary

Published as a supplement to the results publication

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			14/11/2022	No	Yes