PARTICIPANT INFORMATION SHEET

REC Reference Number: HR-17/18-6649

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

STUDY TITLE

IS METACOGNITIVE THERAPY A FEASIBLE TREATMENT OF DISTRESS FOR PEOPLE WITH PARKINSON’S EXPERIENCING MOTOR FLUCTUATIONS?

INVITATION

You are invited to take part in this research study. We want to find out if a new psychological treatment is feasible and acceptable to people with Parkinson’s who experience motor fluctuations. We also want to see if it is potentially helpful before we plan any further research.

It is important you read the following information carefully. This Information Sheet is in two parts. Part 1 explains why this study is being carried out and what taking part in it would involve. Part 2 gives you more detailed information about the conduct of this study and explains what to do next.

After reading this information sheet, please feel free to contact us if you have any questions about the study or what would be involved in taking part. Our contact details are at the end of Part 2 of this information sheet.

PART 1

WHAT ARE MOTOR FLUCTUATIONS AND OFF PERIOD-RELATED DISTRESS?

After taking levodopa (or a similar medication) for Parkinson’s for several years some people develop ‘motor fluctuations’. This means that sometimes their Parkinson’s symptoms are under control (‘on periods’) and other times they are worse (‘off periods’). These fluctuations can occur throughout the day and can be predictable or unpredictable.

Some people can find these fluctuations, and particularly the off periods, distressing. ‘Distress’ can be unpleasant feelings of feelings of low mood, worry, tension, and discomfort. It is often associated with unhelpful and repetitive thinking patterns that serve to make the emotional distress worse and last longer. Research has shown that people who experience motor fluctuations are also more likely to experience distress even during on periods.

WHAT IS METACOGNITIVE THERAPY?

Psychological treatments such as Cognitive Behaviour Therapy can be helpful for treating symptoms such as depression and anxiety. However, at the moment there is no treatment specifically aimed at reducing distress associated with motor fluctuations in people with Parkinson’s.

Metacognitive Therapy is a new type of talking therapy that aims to help people break free from unhelpful and repetitive patterns of thinking and reduce how distressed they feel. Metacognitive Therapy focuses on rumination (i.e., dwelling on thoughts) and worry. It also addresses the things that people pay attention to (such as symptoms) that may also maintain distress.
Research has shown that Metacognitive Therapy is helpful to reduce symptoms of depression and anxiety, but it has not been tested on people with Parkinson’s. However, earlier research suggests the type of things Metacognitive Therapy focuses on are important in off period-related distress in Parkinson’s.

**WHAT IS THE PURPOSE OF THIS STUDY?**

Before Metacognitive Therapy can be recommended we will need to show that it is effective to reducing distress through a clinical trial. However, as with any new therapy, we need to find out whether it is acceptable to people with Parkinson’s and feasible to deliver. We also need to show that it has the potential to reduce distress. The present study aims to assess the acceptability, feasibility and potential of Metacognitive therapy to reduce distress in people with Parkinson’s experiencing motor fluctuations.

**AM I ELIGIBLE TO TAKE PART IN THIS STUDY?**

To take part in this study, you will need:

- To have been received a diagnosis of Parkinson’s disease by a neurologist or other movement disorder specialist
- To be taking dopaminergic medication for your Parkinson’s (such as levodopa) for at least a year
- To experience motor fluctuations for at least the past 12 weeks, spending at a quarter of your day or motor in an off period
- To find your off periods unpleasant and distressing
- To have at least moderate levels of anxiety and/or low mood for periods of time over the past 2 weeks
- To own and routinely use a smartphone and be willing to install an App on it, or be willing to carry a second phone (provided by the research team), for the duration of the study
- To be able to attend weekly sessions at a university in South East London

You will not be able to take part if:

- You have recently started medication for depression or anxiety, or have had your medication adjusted within the past 6-weeks (you may be eligible to take part at a later time)
- You have significant problems with memory and attention that may interfere with you being able to follow the treatment or provide the information required
- You are currently receiving another psychological treatment for depression or anxiety
- English is not your first language and you would typically need the assistance of another person to help you translate

**DO I HAVE TO TAKE PART?**

No, it is entirely up to you whether or not to take part. You can also decide to withdraw at any time without having to explain why. If you decide not to take part, or to withdraw, it will have no effect on the care that you currently receive for your Parkinson’s.

**WHAT WILL HAPPEN TO ME IF I DECIDE TO TAKE PART?**

If you decide that you would like to take part, we first need to check that you meet the conditions described above. This is called ‘screening’. If you meet these conditions you will be able to take part in the study. If you do not meet the conditions at this time you will not be able to take part.

**SCREENING**

We will ask you to complete a brief questionnaire that will tell us about the history of your Parkinson’s, your medication and experience of motor fluctuations, and your current mood. You will complete this questionnaire online and should take no more than 30 minutes. You will also need to provide your name, email address and phone number so you can be contacted by the research team.
After reading Parts 1 and 2 of this information sheet, if you are interested in taking part, you can complete the screening questionnaire on your computer or tablet by going to the web address provide at the end of this document.

Depending on your answers we will contact you to say either that you are not eligible, or invite you attend an appointment with a member of the research team at the study site in Camberwell, south London.

King's College London
Institute of Psychiatry, Psychology and Neuroscience
Henry Wellcome Building
De Crespigny Park
Denmark Hill
London SE5 8AF

The purpose of this appointment is to confirm that you are eligible to take part in this study and to answer any questions that you have about the study before you decide whether or not you want to take part. We will repeat some of the assessments that you completed online and carry out a brief test of memory and attention.

If you are eligible and still want to take part, you will sign a consent form. We will then start the research study and arrange a time for your first treatment appointment.

This appointment will take between 1 to 2 hours.

Research Study

How long does the study take?
The study is designed to take approximately 12-13 weeks in total. However, it may be a bit longer if you have to reschedule any of your appointments.

What does taking part in this study involve?
The study involves the treatment itself and the collection of information that will help us to test whether it is acceptable, feasible and potentially helpful. The treatment involves face-to-face sessions and ‘homework’ practice.

Smartphone App

Both the treatment homework and collection of information involves using a mobile phone.

We will ask you to install a special ‘App’ on your phone. We will help you do this at your first visit and show you how to use it. This App is designed for an Android smartphone phone and does not work on Apple phones. If you do not have an Android phone we will provide you at your first visit for use during the study. If you have an Android phone but do not want the App installed on it, we will provide you with a second phone for the study. It is important that you keep the smartphone charged and carry it around with you throughout the study between the hours of 8:00am and 8:00pm.

All information is stored on the phone and sent to the researchers via the phone’s internet connection. All of the information encrypted and fully secure.

The research team will monitor whether data is being sent by the App to the research study computer. If we have not received any information from you for a day or two, we may contact you by phone or email to check whether there is any technical problem.

Survey questions

During the study the App will present you with brief surveys about how you are feeling throughout the day. The App will alert you to complete the survey four times a day between 8:00am and 8:00pm. The exact timing will be variable.
from day to day. When alerted you can choose to answer the questions straight away, to decline to answer or postpone for a short time.

Each survey will take 3 to 6 minutes to complete. It will ask you questions about your thoughts and feelings at the time the alert goes off, and about your Parkinson’s symptoms – whether you are ‘on’ or ‘off’.

**Questionnaire**
The App will also ask you to compete a longer questionnaire about how you have been feeling over the past 7 days. This will ask similar questions to those you completed during the screening phase. This questionnaire should take no more than 15 minutes to complete each time it is asked (no more than once a week).

**Audio track**
Part of Metacognitive therapy involves improving your ability to focus and switch your attention. We will provide you with an ‘Attention’ training homework task for you to practice once a day at home at a convenient time for you. This will involve listening to a 12-minute recording of everyday sounds and following a series of spoken instruction to help you strengthen your attention. The recording will be stored on the phone for you to use in your practice. We will give you a pair of headphones to use to make the exercises more effective.

**This study has four phases:**

**Phase 1: Pre-treatment (duration: 2 or 3 weeks)**
This phase provides an assessment of how things are before you start treatment. You will use the smartphone App to compete your daily surveys and weekly questionnaire. This phase will last either 2 or 3 weeks.

**Phase 2: Treatment (duration: 6 weeks)**
In this phase you will attend 6 weekly face-to-face appointment at the study site where you will receive Metacognitive Therapy. Therapy sessions will be given by an experienced registered practitioner psychologist. The first session lasts up to 90 minutes and the rest up to 50 minutes. You can bring a family member or friend with you if your wish.

Over the course of the six sessions you will work with the therapist to: (i) understand how your thinking affects your feelings; (ii) practice some mindfulness-based techniques; (iii) explore strategies to help manage with worry and rumination; (iv) work on adjusting some of the unhelpful thinking styles that can maintain distress; and (v) prepare for the end of treatment and how to continue using what you have learned.

With your consent we will audio record your sessions. This is so we can check that the therapy is being delivered properly. You can decline to have the sessions recording or ask for a recording to be stopped and/or deleted.

Between appointments, you will be required to continue to use the App to complete your daily surveys and weekly questionnaire. You will also listen to the 12-minute audio track once a day.

**Phase 3: Post treatment (duration: 2 weeks)**
During this phase you will not be alerted or complete smartphone surveys or questionnaires. You are not required to listen to the audio track but can do so if you choose.

**Phase 4: Follow-up (duration: 2 weeks)**
This is identical to Phase 1. The App will alert you to complete weekly questionnaires and daily surveys. At the end of this period we will ask you some questions about the study and give you the opportunity to share your thoughts about the experience.

**What are the possible benefits of taking part?**
This study aims at helping us decide if Metacognitive Therapy is acceptable and feasible for people with Parkinson’s experiencing motor fluctuations. We do not yet know whether it will help reduce distress. It is possible that you may find some benefit from taking part. However, we do not yet have the evidence to say whether this is likely or by how much.
You may find the study interesting and enjoy taking part in research aimed at helping other people with Parkinson’s.

**IS THERE ANY RISK TO TAKING PART?**

We do not think there are any significant risks for people who take part in this study. The study does involve a significant time commitment over a period of several weeks.

**WHAT HAPPENS WHEN THIS STUDY FINISHES?**

This study is entirely separately from any other care you are receiving. We will not be able to offer any further therapy when the study end and will have no further role in your health care.

When the study is complete we will prepare a report summarising what we have found. If you wish we will send you a copy of this report.

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This completes Part 1 of the Information Sheet.

If you are still interested in taking part in this study, please continue to read the further information in Part 2 (following page) before making any decision.

At the end of Part 2 we explain what to do next if you decide that you would like to take part.
PART 2

WHAT WILL HAPPEN IF I DECIDE I NO LONGER WANT TO CARRY ON WITH THIS STUDY?
You can decide to withdraw from this study at any point without any penalty. With your permission we will retain the data collected up to the point when you chose to withdraw. If you ask within four weeks of stopping the study, we will destroy the data.

HOW IS THIS STUDY BEING FUNDED?
This study is funded by the National Institute of Health Research (NIHR) at the South London and Maudsley NHS Foundation Trust Biomedical Research Centre.

WHAT WILL HAPPEN TO THE RESULTS OF THIS STUDY?
The results will be analysed, along with those of other participants, to help us to decide whether further research is justified and to help us plan further studies. We hope to publish the results of this study in a scientific journal and present them at conferences for other researchers and clinicians. No individual participants will be identifiable in any of the published results or presentations.

WILL MY GP BE INFORMED IF I CHOOSE TO TAKE PART IN THIS STUDY?
Yes. If you consent, we will let your GP know that you are taking part in this study. We will also ask your permission to contact your GP or other healthcare professional if you tell us anything that we think relevant to your care outside the study or after the study has ended.

WILL MY TAKING PART BE KEPT CONFIDENTIAL?
Yes. Your data will be kept confidential throughout the study and afterwards. None of the information will be stored in a way that is linked directly with your name, address or other identifiable information. Your personal details will be stored separately, and the two sets of information linked only by a number. The principal investigator will be the custodian of the research data. In accordance with King’s College London guidance, all research information (paper and electronic) will be kept securely for 10 years, after which time it will be securely destroyed.

CAN I FIND OUT MORE BEFORE DECIDING?
Yes. We would be happy to answer any questions that you may have and provide further information. You can email the investigator at the address given below. If you provide a contact telephone number, he will arrange a time to call you to discuss the study.

WHO HAS APPROVED THIS STUDY?
This study has been assessed and approved by the King’s College London Research Ethics Committee. It is their job to protect your safety, rights, wellbeing and dignity. This study has been reviewed and was given a favourable opinion (reference HR 17/18-6649).
CONTACT INFORMATION
If you have any questions about the study, please contact:

PRINCIPAL INVESTIGATOR

Dr Bruce A Fernie
P1.16
Henry Wellcome Building
De Crespigny Park
London
SE5 8AF
Email: bruce.fernie@kcl.ac.uk
Telephone: 07779 300 427

If this study has harmed you in any way, please contact:

KING’S COLLEGE LONDON: RESEARCH ETHICS COMMITTEE

Chair of the PNM RESC
Research Ethics Committee
Franklin-Wilkins Building
Stamford Street
London
SE1 9NH
Email: pnm@kcl.ac.uk

IF I DECIDE TO TAKE PART, WHAT DO I HAVE TO DO NEXT?
If you are interested in taking part, you can go to the research study website and complete the screening questionnaire using this link.

Click here for online screening questionnaires

Thank you for reading this information sheet and for considering taking part in this research.