

PARTICIPANT INFORMATION SHEET

REC Reference Number: HR-18/19-8816



LENS – Parkinson's Disease

An online study into understanding worry

We would like to invite you to participate in an online research study, funded by Parkinson's UK. Taking part is completely voluntary, and you should only take part if you want to. If you choose not to take part, then this will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what participating will involve, particularly with regards to the time commitment. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information (PwP-research@kcl.ac.uk).

What is the purpose of the study?

We know that many people with Parkinson's feel anxious or worry a lot about lots of different things. This study is designed to help us understand why some people find it difficult to stop worrying. Worrying (thinking about how things might go badly in the future), is normal from time to time, but for most people this passes fairly quickly. However, some people find that once they start worrying, it is very difficult to stop. Research studies have shown that, rather than helping to resolve personal problems, focusing on negative topics in this way can cause anxiety to get worse and to persist longer. However, we know very little about why or how some people are able to control negative thinking while others find it so difficult. In the present study, we hope to learn more about what can make worries so persistent and what people can do to prevent such thoughts getting out of control. Understanding these issues better is important if we are to develop effective psychological treatments for anxiety in people with Parkinson's.

Why might I be invited to take part in this study?

To take part in the study, we are looking for people who:

- have been diagnosed with idiopathic Parkinson's Disease
- often worry about different things
- over the age of 18
- are fluent in English
- living in the United Kingdom or the Republic of Ireland
- have normal or corrected-to-normal hearing
- have access to the internet on a laptop or PC
- have headphones (please contact the research team if you do not)
- can use the computer independently
- have not taken part previously in "Exploring Anxiety in Parkinson's" (study in London run between 2017 and 2018) nor "Thinking Processes in Parkinson's" (online study run in 2018). If you are unsure – we can check for you.

What will happen if I take part?

Suitability checks - If you are interested in taking part in this study, you will first be asked to complete some questionnaires which will help us begin to decide if you are suitable for the study. We will then arrange a phone call with you at a time that suits you. During the phone call, you will be asked some questions to further check the suitability of the study for you.

Main study - If you do meet our criteria, you will be invited to take part in our study. The study is entirely online, so you will not be required to visit us in person. We will provide you with log in details for our website where you will complete a number of assessments and assignments. The majority of these will occur in a three-week period.

Assessments - There will be two assessments during the three-week period and these must be completed on a PC or laptop. The first assessment will take place before starting the first assignment, and the second assessment will take place after completing all assignments (three weeks after completing the first assessment). These assessments will involve completing a number of questionnaires and tasks (lasting around 50 mins), for example a questionnaire about which Parkinson's symptoms you experience, and a task where you have to unscramble sentences to form a coherent sentence. There will be a further two follow-up assessments – one a month after completing all the assignments and another three months after completing all the assignments (lasting around 30 mins).

Assignments – Between assessment 1 and assessment 2, there will be 10 assignments to complete online. We ask that you complete the first assignment either on the same day at the first assessment, or the day after. In the three-week period, you can schedule the 10 assignments however you like, and at whatever time suits you best. You will not be able to complete more than one assignment on a day.

During the assignments you will be listening to short scenarios through headphones, thinking about them in certain ways, and answering questions about them. Scenarios will be everyday situations that you may or may not encounter regularly in real life. There will be practices during the first assignment. Please use a laptop or computer for the first assignment. The subsequent nine assignments will be same as the first one, just minus the practice at the beginning. For the subsequent nine assignments, you can use a tablet if you prefer. Please make sure you complete assignments at a time when you will not be disturbed. Each assignment will take about 40 minutes (except for the first one, which takes about 50 mins).

Reminders – During the study we will send you reminders to complete your assignments. We will also be in contact (by email, phone or text, depending on your preference) over the course of the three weeks to find out how you are getting on.

Phone call – A main aim of this research is to find out whether this online, multi-session design of the study is suitable in a Parkinson's population. Therefore, after completing the second assessment, we will invite you to take part in a telephone interview to ask you some questions about your experience with the research. In order to accurately note your feedback, this phone call will be recorded so that we can collate and analyse all feedback thoroughly (no identifying information will be included in the recording).

What are the possible disadvantages of taking part?

The study involves thinking about some current worries. Some people might find some of these tasks uncomfortable or mildly distressing, but that feeling will go away once the task stops and will have no long-term impact. If the study brings up any concerns, you will have the opportunity to discuss them with the researcher over the phone or via email. Participating in the study will involve some of your time, as described above, to complete the assessment sessions, assignments and the follow-up questionnaires. You may find completing the study slightly tiring, but you can schedule the assessments, assignments and phone calls at a time that suits you best. Furthermore, you will be free to withdraw from the study at any point if you wish to do so.

What are the possible benefits of taking part?

We hope that you will find it interesting to take part in this research. Also, the information we get from this study should help us to understand more about why some people with Parkinson's cannot stop worrying and how we may be able to help them overcome this. Because research of this kind addresses questions to which we do not yet know the answers, it is impossible to know if taking part will be personally helpful, although we certainly hope that some of the techniques involved will help participants to worry less. As this study is funded by Parkinson's UK, resulting publications in scientific journals will also be available on the Parkinson's UK website.

What if I change my mind about taking part?

You are free to withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way. You will be asked if you want to provide a reason, but you do not have to should you not want to. If you would like us to remove all data that you have provided so far, please indicate this to a member of the research team. Once the study has ended (30.11.2019), all data will be anonymised, and it will therefore not be possible to remove your data. If you do wish to withdraw from the study, you may do so by contacting a member of the research team (details provided below).

Will my taking part in this study be kept confidential?

Information which is collected about you during the course of the research, including audio recordings, your answers to questionnaires and the online tasks, will be kept strictly confidential. This means you will be given a participant number and that the only way to identify you will be by your numerical ID, to ensure anonymity. All information will be kept strictly confidential unless any information is disclosed which could seriously affect the welfare of yourself or others, in which case a third party may have to be contacted for legal reasons.

By November 30th 2019, or earlier if the recruitment target (60) has been met, all data will be anonymised meaning it will not be possible to trace any of the data back to you.

These data will be stored securely in anonymised form on a password-protected computer in King's College London for up to seven years. Data will only be seen by members of the research team.

What will happen to the results of the research study?

The findings will be used to improve psychological treatments for anxiety in people with Parkinson's. The results of the study will be published in a peer reviewed journal, presented at conferences and discussed at other public events. Individual data will not be reported and you will not be identified in any report or publication. We may quote what you have said during the feasibility interview to

illustrate some of the findings, however we will ensure that we will not quote any details that could be used to identify you.

Who has reviewed the study?

The research has been approved by the Psychiatry, Nursing and Midwifery Research Ethics Subcommittee at King's College London (ref no: HR-18/19-8816).

It is up to you to decide whether to take part or not. If you decide to take part, you will have access to this information sheet and will be asked to complete an informed consent form once before completing the suitability questionnaires and once before you start the first assessment session. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

For general queries about the study, please contact one of the researchers at PwP-research@kcl.ac.uk or on 0207 848 5025.

This study is being conducted by Dr Lonneke van Tuijl, a researcher at the Institute of Psychiatry, Psychology and Neuroscience at King's College London. To contact her, you can send an e-mail to Lonneke.van_tuijl@kcl.ac.uk. Postal address: Department of Psychology (PO77), King's College London, De Crespigny Park, London, SE5 8AF. Please feel free contact her if you have any questions or queries.

Alternatively, if you have any concerns about the study, please contact one of the lead investigators: Professor Richard Brown (Richard.g.brown@kcl.ac.uk Tel no: 02078480773) or Dr Colette Hirsch (Colette.hirsch@kcl.ac.uk Tel no: 02078480697).

If this study has harmed you in any way, you can contact the Chair of the Psychiatry, Nursing and Midwifery Research Ethics Subcommittee on pnm@kcl.ac.uk.

Data Protection Statement

The data controller for this project will be King's College London (KCL). The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a 'task in the public interest'. You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability.

Questions, comments and requests about your personal data can also be sent to the King's College London Data Protection Officer Mr Albert Chan info-compliance@kcl.ac.uk. If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk.