



Participant Information Sheet for people living with Parkinson's and anxiety (v2, 17/10/2023)

UCL Research Ethics Committee Approval ID Number: 12213-006.

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET TO KEEP.

Title of study: Adapting Acceptance and Commitment Therapy for people living with Parkinson's and anxiety.

Department: Division of Psychiatry, UCL

Name and Contact Details of the Researcher(s): Professor Rebecca Gould (r.gould@ucl.ac.uk), Professor Suzanne Reeves (suzanne.reeves@ucl.ac.uk), Professor Anette Shrag (a.schrag@ucl.ac.uk), Dr Joshua Stott (j.stott@ucl.ac.uk), Ms Natasha Lyons (natasha.lyons.18@ucl.ac.uk)

Name and Contact Details of the Principal Researcher: Professor Rebecca Gould (r.gould@ucl.ac.uk)

1. Invitation to participate in a research study

You are being invited to take part in a research study, which is being conducted by Professor Rebecca Gould and Professor Suzanne Reeves (Division of Psychiatry, UCL), Professor Anette Schrag (Institute of Neurology, UCL), Dr Josh Stott (Department of Clinical, Educational and Health Psychology, UCL) and Ms Natasha Lyons (Division of Psychiatry, UCL).

Before you make a decision, it is important for you to understand why the study is being carried out, and what it will involve. Please take your time to read the following information carefully and decide whether or not you wish to take part. Please discuss it with others if you wish. Please feel free to email us if there is anything that is not clear or if you would like more information. Thank you for reading this.

2. What is the purpose of the research study?

The purpose of this study is to develop a set of recommendations as to how we can adapt a newer form of talking therapy, Acceptance and Commitment Therapy, so that it meets the specific needs of people living with Parkinson's and anxiety. Acceptance and Commitment Therapy is a form of talking therapy that helps people to learn new ways of dealing with distressing thoughts, feelings and bodily sensations. It also helps people to engage in behaviours that they find personally meaningful alongside distressing thoughts, feelings and bodily sensations.

Acceptance and Commitment Therapy has been found to be helpful for improving wellbeing in other conditions including other neurological conditions (such as muscle disorders and epilepsy). It may be particularly suited to people living with Parkinson's and anxiety due to its focus on helping people to live their lives in ways that are important and matter to them, alongside any unpleasant or distressing symptoms, sensations, thoughts or feelings that may come with this.

We will use the recommendations from this study to develop an intervention based on Acceptance and Commitment Therapy specifically for people living with Parkinson's and anxiety in the future.

3. What is anxiety?

Symptoms of anxiety include feeling anxious or nervous, feeling restless or on edge, worrying a lot about different things, increased heart rate, shortness of breath, sweating, feeling panicky and having a sense of impending danger or something bad happening.

4. Who are we approaching to take part in this study?

We are asking approximately 15 people who meet the following criteria to take part in this study:

- Aged 18 years or more;
- Diagnosis of Parkinson's made by a healthcare professional (such as a neurologist);
- Currently experiencing anxiety symptoms;
- Sufficient ability to understand English to complete an interview;
- Willing to take part in an interview and be audio recorded.

You are reading this Participant Information Sheet because you have: 1) self-identified as having a diagnosis of Parkinson's; 2) self-identified as currently experiencing difficulties with anxiety; and 3) expressed an interest in taking part in the study.

If you are still interested in taking part in the study, then you will be invited to take part in a telephone call to ensure you are eligible to take part. During this telephone call, we will confirm that you meet the criteria listed above, with your verbal consent.

If you meet the eligibility criteria then we will discuss the Participant Information Sheet with you and you will be given the opportunity to ask questions about it. You will be given as long as you need to consider this information.

If you would like to take part in the study then you will be sent an informed consent form via email, post or an online, secure, web-based e-consent platform called REDCap. You will be asked to sign and return this to the researcher (either via email, post in a pre-paid, addressed envelope or REDCap). Once the signed informed consent form is received, we will discuss how you would like to take part in the interview with you (either via video call or telephone) and arrange an appointment for it.

5. Do I have to take part?

It is up to you to decide whether you would like to take part in this study. If you do decide to take part, then you will be given this information sheet to keep and be asked to sign a consent form. You can decide not to take part in the study or you can stop it at any time, without giving a reason and without it affecting your medical care or legal rights. If you decide to withdraw from the study then you will be asked what you wish to happen to the data you have provided up to that point. You will be able to withdraw your data up to 4 weeks after the interview.

6. What will happen to me if I take part?

Length of time: Approximately 60 minutes.

Location: Video call or telephone.

You will be asked some questions about yourself, including your age, self-identified gender, ethnicity, education, self-reported difficulties with Parkinson's and your mood. This is so that we can describe the sample of participants who have taken part in this study and see whether they are similar to the wider population of people with Parkinson's in the UK.

Examples of the type of questions you will be asked in relation to your experience of Parkinson's are: "Over the past week, have you usually had shaking or tremor?" and "Over the past week, have you had trouble staying awake during the daytime?".

Examples of the type of questions or statements you will be asked in relation to your mood are: "In the past four weeks, to what extent did you experience the following symptoms? Feeling anxious or nervous" and "In the past four weeks, to what extent did you experience the following symptoms? Fear of something bad, or even the worst, happening".

You will then be asked some questions about factors that may hinder or help people living with Parkinson's and anxiety to take part in Acceptance and Commitment Therapy, and how we can adapt Acceptance and Commitment Therapy for people living with Parkinson's and anxiety.

Examples of the type of questions you will be asked are: "One of the aims of Acceptance and Commitment Therapy is to help people learn skills for unhooking from distressing thoughts, feelings and bodily sensations in order that they can do the things that are important and matter to them. What do you think about that?" and "Talking therapy can be delivered online, via a smartphone app or in person. Which option do you think would be best for people living with Parkinson's and anxiety?".

You will be able to stop the interview at any point, without having to give a reason. If you complete some but not all of the interview then we would use any information that you provided up to the point that you stopped. If there are particular questions that you would prefer not to answer then you will be able to indicate this in the interview, without having to give a reason.

7. Will I be recorded and how will the recorded media be used?

Your interview will be recorded on an encrypted and password-protected digital voice recorder. The audio recording of your interview will only be used for analysis. No other use will be made of your recording without your written permission, and no one outside the project will be allowed access to the original recording. Written quotes from your interview may be used when we publish the results, but these will not include any identifiable information.

8. What are the possible disadvantages and risks of taking part?

Some people may find it upsetting answering questions in relation to their experience of Parkinson's or their anxiety. If you find a particular question upsetting, you can choose not to answer it, take a break from completing the interview, or stop the interview altogether. If you become distressed during the interview then you will be able to discuss this with the interviewer. You will also be given information about sources of support with respect to Parkinson's or anxiety at the end of the interview (or whenever you decide to stop it). In addition, you will be able to contact Professor Rebecca Gould (r.gould@ucl.ac.uk). Professor Gould is an honorary clinical psychologist within Services for Ageing and Mental Health, Camden and Islington NHS Foundation Trust. Any email contact will usually be responded to within five working days.

You may also feel tired during the interview and so you will be able to take regular breaks during the interview, complete the interview in multiple sessions, if you prefer this, or stop the interview altogether. Your participation in this study is voluntary and you may withdraw from the study at any time without having to give any reason as to why and without it affecting your medical care or legal rights.

9. What are the possible benefits of taking part?

Whilst there are no immediate benefits for those people participating in this research study, this work will enable us to develop an intervention based on Acceptance and Commitment Therapy that is specifically adapted for people living with Parkinson's and anxiety in the future. Ultimately, it is hoped that this will help us find better ways of helping people living with Parkinson's and anxiety to manage their symptoms.

10. What if something goes wrong?

If you have a complaint about this study or are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution. If there is a problem or if you have any concerns about the way you have been approached or treated in this survey, then please contact Professor Rebecca Gould, Department of Psychiatry, University College London, Wing B, 6th floor Maple House, 149 Tottenham Court Rd, London W1T 7NF. Tel: 020 7679 9925. Email: r.gould@ucl.ac.uk.

If you remain unhappy and wish to complain formally about any aspect of the way you have been approached or treated during this survey, then please contact the Chair of the UCL Research Ethics Committee at ethics@ucl.ac.uk.

11. Will my taking part in this project be kept confidential?

All the information that we collect about you during the course of this research study will be kept strictly confidential. You will be assigned a unique identification number so that it will not be possible to identify you from any of your information, which will be used in all data storage. This will not contain any names or personally identifiable information. Contact details will be stored in a separate password-protected file which only the lead researcher will have access to. You will not be able to be identified in any ensuing publications. Any quotes from interviews used in the write up of this research will be anonymised and identifying information will be removed.

An encrypted digital voice recorder will be used to record your interview. The audio file will be deleted from the recording device as soon as it is stored on UCL's password-protected secure electronic network. The audio file will be securely deleted from UCL's password-protected secure electronic network as soon as the interview is transcribed by the interviewer, anonymised and checked for accuracy.

All electronic data will be held on a password-protected database, processed on a password-protected computer, and stored on UCL's password-protected secure electronic network for 10 years from the end of the study, along with any anonymised notes taken during interviews and anonymised transcripts. Only members of the research project who need access to the database, anonymised notes and transcripts will be granted access.

Please note that assurances on confidentiality will be strictly adhered to unless evidence of wrongdoing or potential harm is uncovered. In such cases the University may be obliged to contact relevant statutory bodies/agencies.

12. What will happen to the results of the research project?

At the end of the study, we will analyse all your information with other participants' information. We will then hope to publish our findings in an academic journal. We will send you a summary of the findings if you request this. You will not be identified in any publication arising from this study.

13. Local Data Protection Privacy Notice

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice:

For participants in research studies, please click [here](#) or go to:

<https://www.ucl.ac.uk/legal-services/privacy/ucl-general-research-participant-privacy-notice>

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The categories of personal data used will be as follows:

- i) Questions about your contact details (name and email address, telephone number or address);
- ii) Questions about yourself such as your age, self-identified gender, ethnicity, and education;
- iii) Questions about your health (self-reported difficulties with Parkinson's and mood).

The lawful basis that will be used to process your personal data will be 'public task' in the public interest. The lawful basis that will be used to process your special category personal data will be 'research purposes'.

Your personal data will be processed so long as it is required for the research study and for publication of the research findings. We will undertake to anonymise or pseudonymise the personal data you provide, and will endeavour to minimise the processing of personal data wherever possible.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

14. Will my data be shared with anybody else?

Your anonymised data, not containing personal identifiers, may be used to support other research in the future, and may be shared with other authenticated researchers from organisations such as universities or NHS Trusts in the UK. Your information will only be used by organisations and researchers in accordance with the UK Policy Framework for Health and Social Care Research.

It will not be possible to identify you from your data, and it will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

15. Who is organising and funding the research?

The research is sponsored by University College London.

16. Who has reviewed the study?

All research is looked at by an independent group of people, called a Research Ethics Committee in order to protect participants' safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by UCL Research Ethics Committee (reference number: 12213-006).

17. Who can I contact for further information?

If you have any questions or require any further information about this study then you can contact Professor Rebecca Gould at: Division of Psychiatry, University College London, Wing B, 6th floor Maple House, 149 Tottenham Court Rd, London W1T 7NF; 020 7679 9925; r.gould@ucl.ac.uk.

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