

PARTICIPANT INFORMATION SHEET

REC reference number: ETH2223-1570

Title of study: Evaluating a psychological support app for Parkinson's

Name of principal investigator: Cathryn Pinto (Cathryn.pinto@city.ac.uk)

We would like to invite you to take part in a research study. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you. Please read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is unclear or if you would like more information.

What is the purpose of the study?

We would like to trial an app that we developed which can be used to support the psychological well-being of people with Parkinson's. The purpose of the research is to assess if the app is relevant and acceptable to people with Parkinson's and to test whether the app is potentially effective for improving wellbeing. We would like to do this by conducting a small trial where some people with Parkinson's will be given access to the app and others will receive care and support as they usually would. We will then compare the two groups on several aspects of wellbeing to see if using the app made a difference. We also want to know if the app is acceptable and may make further refinements based on people's experience using it.

What is the app about?

The app has short activities that can be used regularly to help you feel better and improve your psychological wellbeing. It can be used on a smartphone, tablet or computer and includes audios, videos, and self-reflection activities. The activities and information are based on a type of therapy called Acceptance and Commitment Therapy (ACT for short) which can help you deal with difficult thoughts and feelings and encourages you to do more activities that are important to you and in line with things you value. The app has been developed together with a group of people who have Parkinson's disease and their family members or carers. It has been designed so that it is easy to use with different Parkinson's symptoms.

Why have I been invited to take part?

This study has been advertised to people with Parkinson's who might be interested in using an app to improve their wellbeing. It is completely voluntary to take part. To participate, you will need to have a Parkinson's diagnosis, have an electronic device (e.g. computer or smartphone or tablet) to be able to use the app, and experience some difficulty with emotional



wellbeing (as measured through a questionnaire). You do not need to be an expert in using technology or apps. We intend for the app to be used by people with different levels of familiarity and comfort with technology. If the app is not easy to use, your feedback will help us improve it for other people who may not be as comfortable with technology.

Do I have to take part?

No, participation in this project is voluntary. It is your choice to decide to take part or not and this will not have an impact on the care you receive from your neurology team or from Parkinson's UK. If you do decide to take part you will be asked to sign a consent form. You can withdraw at any stage of the project without being penalised or disadvantaged in any way. You can withdraw by sending an email to the researchers mentioned in this information sheet or by telling them verbally of your intention to withdraw, and you don't need to give a reason for your withdrawal. However, once the data has been analysed (i.e. after Feb, 2024), you will not be able to withdraw your data as it will have already been de-identified (i.e. identifying information will be removed from the data) so it can be used for analysis.

What will happen if I take part?

Step 1 – Answer some screening questions: If you have read this information and would like to participate, you can email the researcher (Cathryn.pinto@city.ac.uk). Cathryn will then arrange a call with you to ask you some questions to make sure you are eligible to take part in this study and answer any questions you might have about taking part.

Step 2 – Fill in the consent form and baseline questionnaire: You will be asked to fill in a consent form and a baseline questionnaire which requires some demographic information and details about your Parkinson's diagnosis and symptoms. These forms will be sent to you via email and can be completed online.

Step 3 – Group allocation: At this stage, you will be randomly assigned to either an intervention group (i.e. the group that uses the app) or a control group (i.e. the group that uses care as usual). The intervention group will receive details about how to access and use the app. The control group will not receive access to the app during the trial. At the end of the trial period (not later than Feb. 2024), we will offer participants in the control group a chance to use the app if they'd like to.

Step 4 – Trial period (4 weeks): During these 4 weeks, if you are in the intervention group, you will use the app daily for 5-10 mins (or as regularly as possible) and try out the different tips and suggested activities. If you are in the control group, you will continue receiving care and support as you usually would. We will ask you about the support you received including any other psychological support that you may have used during this 4-week trial period.

Step 5 – Final questionnaires: At the end of the 4 weeks, you will be sent an email with links to complete the final questionnaires for this study. If you are in the intervention group, at this stage you may also be invited to give us further feedback by taking part in an interview via videocall or telephone. If you are in the control group, you will receive access to the app at this stage once the final questionnaires are complete.

What are the possible disadvantages and risks of taking part?

It is unlikely that you will experience any harm by taking part in the study and using the app. If you do find that using the app causes you any discomfort, distress, or concern, you are free



to stop or withdraw at any time. We can also help share some resources or contact your neurology team for any further assistance.

What are the possible benefits of taking part?

We hope that using the app and learning some of the tools and activities can help you manage any emotional struggles you may have and help with your wellbeing. If we find that this app is effective, we hope to roll it out so that other people with Parkinson's may also benefit from it. We also hope that you will find it interesting to take part and learn of the results.

How is the project being funded?

The project is being funded by a grant from Parkinson's UK.

What should I do if I want to take part?

If you would like to take part, please let the researcher (Cathryn.pinto@city.ac.uk) know via email.

Will my taking part in the study be kept confidential?

All your personal data (i.e your name and contact details) will be kept strictly confidential. Personal data will be stored on a secure computer database at City, University of London. Only authorized individuals from City University (and from the University of Glasgow) directly involved with the study will have access to this data. We will use a unique number rather than your own name to de-identify your responses to the different questionnaires. This de-identified data will be shared with members of the research team at other organisations and stored in an open-access repository for future use by the wider research community.

We will comply with the University's policies to ensure confidentiality of the data throughout the process. We will not divulge your responses to your healthcare team without your permission. Suppose you tell us something that gives us concern about your safety or the safety of another person, we may have to pass that information to a relevant healthcare professional.

Who is the research team and how will my data be shared?

The research team includes staff from different universities and organisations. Most of your correspondence will be with Dr. Cathryn Pinto from City University of London. Your data may be shared with Dr. Angeliki Bogosian, Dr. Catherine Hurt, and Dr. Jennie Brown from City University of London, who will also assist in running the trial. Your email addresses will be shared with Dr. Simone Stumpf and Ricardo Volpato from the University of Glasgow to help you log in to the app, monitor technical aspects and enable the smooth running of the app during the trial. Your anonymized data will be shared with Dr. Sam Norton who is our statistician from King's College London, Prof Lance McCracken from Uppsala University who is a clinical health psychologist, Dr. Patricia Cubi-Molla from Office of Health Economics who is a health economist, and Kirsten Turner who is a Parkinson's Nurse Specialist from North East London NHS Foundation Trust.

What will happen to the results?

The data collected will be written up for publication in academic journals and reported at conferences. You will not be named in any study report or publication. We may also share our results by publishing articles online or via Parkinson's UK research network.



Who has reviewed the study?

This study has been approved by City, University of London, Senate Research Ethics Committee, reference number ETH2223-1570.

What if there is a problem?

If you have any problems, concerns or questions about this study, you should ask to speak to a member of the research team (Cathryn Cathryn.pinto@city.ac.uk or Angeliki Angeliki.bogosian.1@city.ac.uk). If you remain unhappy and wish to complain formally, you can do this through City's complaints procedure.

To complain about the study, you need to email SenateREC@city.ac.uk and inform them that the name of the project is *Evaluating a psychological support app for Parkinson's*.

Data privacy statement

City, University of London is the sponsor and the data controller of this study based in the United Kingdom. This means that we are responsible for looking after your information and using it properly. The legal basis under which your data will be processed is City's public task.

Your right to access, change or move your information are limited, as we need to manage your information in a specific way in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personal-identifiable information possible (for further information, please see <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/public-task/>).

City will use your name and contact details to contact you about the research study as necessary. If you wish to receive the results of the study, your email address will also be kept for this purpose. City will keep information without your name for 10 years after the study has finished. The questionnaire responses and interview transcripts without your name will be saved in a database and future researchers could have access to the data. You can find out more about how City handles data by visiting <https://www.city.ac.uk/about/governance/legal>. If you are concerned about how we have processed your personal data, you can contact the Information Commissioner's Office (IOC) <https://ico.org.uk/>.

Insurance

City University London holds insurance policies which apply to this study, subject to the terms and conditions of the policy. If you feel you have been harmed or injured by taking part in this study, you may be eligible to claim compensation. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for legal action.

Further information and contact details

If you are interested in taking part in this study but would like some more information before you decide, please contact Cathryn (Cathryn.pinto@city.ac.uk)

Thank you for taking the time to read this information sheet.