UNIVERSITY OF PLYMOUTH

Participant Information Sheet

Using a Delphi process to inform the design of disease modifying trials in Parkinson's disease

1. Invitation

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

It is important that you consider carefully, whether you will be able to complete the study as its success depends on you completing every single survey included in the study.

Please ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

2. What is the purpose of the study?

Under the leadership of Dr Camille Carroll at the University of Plymouth, and in collaboration with the Cure Parkinson's Trust, this study aims to develop new ways of testing treatments that might slow or stop progression of Parkinson's. Currently, clinical trials test one drug at a time, which means it takes several years before it is known whether a drug benefits people with Parkinson's. This study will be used to develop a 'platform' trial, in which several drugs can be tested at once. If any drug is found not to have benefits, then a new drug would be added in. If a drug is found to be helpful, then it can be taken forward into the clinic much quicker. The platform would run for many years and to be successful, there has to be agreement on how the trial is structured.

The purpose of this study is to collect opinions from different people involved in clinical studies in Parkinson's, to try and reach agreement as to what is important and what might work well. This will be achieved by a Delphi Process (explained below). The results of the Delphi Process will be used to help design a platform trial of protective therapies in Parkinson's.

3. What is a Delphi Process?

In this Delphi Process, you will receive a questionnaire in which you will be asked to give a score to a series of statements, to show how important something is to you when considering to get involved in a trial. You will be asked to explain your scores. The research team will analyse everyone's responses and then ask you to score the same statements again – this time letting you see how other people in the survey scored the statements and why. No-one in the group can see another individual's scores; they can only see the overall results for the group as a whole. Using this information you will be asked to reflect on your own view and on the view of the group and decide whether to stick with your original score or change it. Through the whole process you are under no pressure to change your score if you don't want to. It is perfectly fine for you to score differently to the rest of the group.

4. Why have I been invited to take part?

You have been asked to take part because you are someone with Parkinson's, caring for someone with Parkinson's, a clinical scientist, or a representative from the pharmaceutical industry, funding agency or regulatory agency. These are the groups of people with an interest in Parkinson's trials of protective therapies.

5. Do I have to take part in the study?

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to give consent to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason.

6. What will I be asked to do if I decide to take part?

If you decide to take part in this research study and you are selected to take part, you will receive a link with the survey invitation. This will take you to the survey website where you will be asked to give consent to take part in the study and then proceed to the survey.

You will have 4 weeks to complete the survey**.** You will be able to save your responses and return to complete the survey at a later time if you need to. However, you must complete the survey within 4 weeks or you will have to be removed from the study.

We will send you two emails during this time to remind you to complete the survey, if you haven't done so already and may phone you, if you register your contact phone number.

You will receive the survey a maximum of 5 times over the next 6 months. Apart from the first survey, you will also receive a summary of feedback from all participants. Each survey should take no longer than 20 minutes to complete. There will be 2 weeks between survey closure and the launch of the next survey, to allow the study team to analyse and prepare anonymised feedback.

You will be given the option to tell us if you can not answer a question. If this is the case we will give you the option to explain to us why you were unable to answer it. For example, you can let us know whether you did not have enough information or found the question confusing. This will help us to make the question clearer for the next survey round.

It is important that you consider carefully, whether you will be able to complete all rounds of the survey. If you decide not to complete one of the surveys, which is your right, results from your prior participation can not be used in the final result of the study. The success of the study depends on you completing every single survey.

7. What are the possible benefits of taking part?

There are no direct benefits to you in taking part in this research. You will be helping us to design a new type of clinical trial to speed up the testing of protective therapies in Parkinson's.

8. Will my taking part in this study be kept confidential?

All information collected about you during the course of this study will be kept strictly confidential. We will store your data using a unique code rather than your name. All information will be stored securely on a password protected University computer.All information will be handled in compliance with the General Data Protection Regulations (2018).

Your name and contact details (which we will need in order to contact you) will be stored separately from the other information you supply during the study so that you cannot be identified from your study records.

Privacy Notice for Participants

The University of Plymouth is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Plymouth will keep study data for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the research data you have already provided.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the University's Data protection Officer.

The University's Data Protection Officer can be contacted by e-mailing: dpo@plymouth.ac.uk
For more information about research and about general use of data collected for research please refer to:

https://www.plymouth.ac.uk/uploads/production/document/path/6/6913/Research_Data_Policy.pdf

9. What will happen if I don't want to carry on with the study?

If you decide you do not want to carry on with the study, you may withdraw at any time and without giving a reason (although we may ask you for a reason, to help us design better studies for the future, it is up to you whether you are happy to supply a reason or not). If you withdraw, we will keep any information you have already provided.

10. Will the study information help with other research projects?

Working groups will be set up to design the new trial in Parkinson's, and they will be given the research data collected by the study to guide their work.
Information will be made available under an appropriate data sharing agreement, but it will not be possible to identify you personally from any information shared.

11. What will happen to the results of this study?

After the study is completed, you will be sent a summary of the main findings.

The results will be used to help us understand what is important for designing Parkinson's trials. Working groups will be set up to design a new trial in Parkinson's, and they will be given the results of the study to guide their work.

The results will be published in scientific journals and presented at conferences. We will work with people with Parkinson's to ensure that the results are publicised as widely as possible.

12. Who is organising and funding this study?

This study is being organised by the University of Plymouth. The study is funded by the Cure Parkinson's Trust.

13. Who has reviewed the study?

This study has been designed together with and reviewed by people with Parkinson's disease. It was further reviewed by the Faculty of Health: Medicine, Dentistry and Human Sciences Research Ethics Committees at the University of Plymouth. If you have any concerns or questions about the ethics of the research or about any aspect of the study, please contact:

Mo Bottomley, Research Administrator, Faculty of Health: Medicine, Dentistry and Human Sciences, University of Plymouth, 4th Floor Rolle Building, Drake Circus, Plymouth, PL4 8AA
Tel: 01752 586992 Email: hhsethics@plymouth.ac.uk

14. Contact for further information

You are encouraged to ask any questions you wish, before, during or after the study. If you have any questions about the study, please speak to any member of the research team, who will be able to provide you with further information. If you require any further information or have any concerns while taking part in the study, please contact a member of the research team.

Study Coordinator

Name: Marie-Louise Zeissler

e-mail: pdmams@plymouth.ac.uk
phone:+44(0)1752434293

Chief Investigator

Name: Dr Camille Carroll

e-mail: pdmams@plymouth.ac.uk
phone: +44(0)1752439829

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