

Participant Information Sheet

Version 3.4 02/02/2017

Title of research study:

Care of Late Stage Parkinsonism (CLaSP Study)

Name of Lead Researcher: Prof. Anette Schrag

You are being invited to take part in a research study. This leaflet explains why the research is being done and what taking part will involve. Please read the following information carefully and discuss it with others if you wish. You can then talk to the researchers before you decide whether to go ahead. Thank you for taking the time to read this.

What is the study about?

The aim of this study is to determine the needs of those who have had Parkinsonism for a number of years, and their carers. We are interested in how needs are currently met in different European countries, and how care could be improved. We suspect that there are unmet needs and that these can be addressed better. We will therefore assess the problems and needs of those who have had Parkinsonism for a number of years, and their carers, through examination and questions; and by looking at existing health care databases. We will also study the effect of a specialist clinician making an assessment and treatment recommendations compared to those who receive their normal care.

In addition, we are collecting saliva samples in order to allow genetic analysis by ourselves or our collaborators in future studies that are approved by a Research Ethics Committee. These samples will help us study markers that could help in the future diagnosis of Parkinson's disease or in monitoring how the condition progresses.

Why have you been invited?

You have been invited because you have had Parkinson's disease or Parkinsonism for at least seven years. We are writing to everyone who has been diagnosed for that length of time as everyone has different experiences of Parkinson's. We are particularly looking for people whose health, movement and daily life have been significantly affected after this length of time with the condition.

What does taking part involve?

- Someone from the research team will talk to you about the study. If you agree to take part the researcher will also ask you a few questions to assess your memory, understanding and physical ability.
- A member of the research team will contact you to make an appointment for an assessment. The assessment can be in your home or in a hospital clinic, if you prefer.

- The appointment will involve an assessment of your movements as well as answering questions about your health, memory, circumstances, the health care you receive, previous treatments, as well as questions about your general needs. The researcher will ask you if they may video or audiotape some of your movements and replies in the interview. They will also take your lying and standing blood pressure.
- The researcher will also ask you for a saliva sample. If this is not possible at the first face-to-face assessment the researchers will post you a sample kit to your home with full instructions on how to use it.
- The assessment should take approximately 2 hours, but this can be carried out in two appointments if you prefer.
- The researcher will ask your carer, relative or friend, if applicable, to complete a questionnaire about your usual activities and behaviour and ask them questions about your and their needs and the health care you receive.
- They will also ask your health care provider or member of staff about your medical problems and treatments.
- After the assessment the researcher will discuss the findings with a specialist in movement disorders who will also watch the video made of your movements and the replies given to questionnaires.
- If you agree, and are eligible, you will then be given the opportunity to participate in the open trial. This would mean that you will either receive your usual care, or the research doctor will contact your primary care physician to inform them about the assessment results and make recommendations about possible changes to your treatment and care. During this time you and your healthcare providers would also have access to a helpline. You will be offered up to 3 further assessments and the last two assessments can be in person or via the telephone.
- We do not know whether having a specialist assessment in this way in addition to normal care will make a difference to health for those who have had Parkinsonism for a number of years. To find this out one quarter of participants will continue with their usual care and three quarters of participants will receive a closer review of treatment.
- The choice of which group you will be in is completely random. You and your doctor will know which group you are in but not all of the researchers will necessarily know which group you are in. Whichever group you are in a letter with the assessment results will be sent to your GP.
- The researchers would like to carry out semi-structured interviews with a number of participants and carers. This would take the form of an interview about the needs, experiences and health-care support of those who have had Parkinson's for a number of years. The option of taking part in this aspect of the study will be discussed with you at your assessment.
- Your confidentiality is very important to us. The information you give during this study will be used in strict confidence by the people working on the study. Your personal information will not be released under any circumstances other than to your health care team. However, we will share data with the researchers from other countries to enable comparisons to be made between health care systems, but this will not be any personal details that could identify you.

What are the possible risks of being in the study?

The study will require a commitment in time and you may find the assessment lengthy. However, there will be breaks and you can ask to stop the assessments at any point.

How does this study benefit me?

The care of those with Parkinson's disease can often become difficult as the disease progresses. This is partly due to difficulty accessing health care services and the complexities of the disease. This study aims to establish the best ways to improve care in Parkinson's. This will be done by providing information about met and unmet needs, and the current management and availability of health care resources. Although taking part may not directly benefit you at the time, the study findings will provide international guidelines that will benefit those with Parkinsonism and their carers.

Similarly, whilst providing a saliva sample will not benefit you directly the information we obtain from it may mean we learn more about Parkinson's. We hope this might help to treat people better in the future.

Do I have to take part?

You do not have to take part in the study and it is entirely up to you whether you want to take part or not. You do not have to give a reason if you do not want to be involved. Whatever you decide will have no effect on the care you receive now or in the future. If you agree to take part but then change your mind you can withdraw from the study at any time without giving a reason. If you do withdraw, you can decide whether we can use any information you have already given us.

Expenses

If you agree to take part in this study and you choose to have the assessment done at a hospital clinic we will cover your travel expenses by car or taxi. If you are accompanied by a relative, friend or carer, their travel expenses will also be paid.

Personal information policy

If you decide to take part in the study, all information that you provide to us and the results of the study will be treated confidentially. Information will be stored securely in locked cabinets and password protected computer systems which can only be accessed by the research team.

The saliva sample will be stored securely within appropriate storage facilities and without any identifying personal details, in accordance with rules by the Human Tissue Authority.

We will write to your General Practitioner (GP) with your permission informing them of your agreement to take part in this study. If you are in the treatment arm of the study, a summary with recommendations will be sent to your GP and/or specialist.

The NHS is improving the quality of clinical and research standards. This is being achieved through 'clinical governance'. As part of this process, this study may be reviewed by a clinical governance team. Such a team would need to look at your records to make sure that the research was carried out in accordance with proper procedures. If this takes place your information will remain confidential during this process.

What if there are any problems during the study?

Every care will be taken to ensure that your well-being and safety is not compromised. If however you or your relatives have any concerns about the research study you can speak to a member of the research team who will do their best to answer any

questions. Contact details are at the end of this information sheet. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff when participating in the research, National Health Service or University College London (UCL) complaints mechanisms are available to you. Please ask a member of your research team if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available to you. If you suspect that the harm is the result of the Sponsor's (UCL) or the hospital's negligence then you may be able to claim compensation; UCL has a special insurance arrangement in place (no-fault compensation). After discussing with your research team, please make the claim in writing to Prof. Anette Schrag who is the Chief Investigator for the research and is based at the UCL Institute of Neurology, who will then pass the claim to the Sponsor's Insurers. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this. NHS Indemnity does not offer no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm. All communication will be dealt with in the strictest confidence.

Who is organising and paying for the study?

The study is funded by the Economic and Social Research Council (ESRC) of the UK, in collaboration with similar funding bodies in other European countries which are also participating in this study

The research team you will have contact with is mainly based at the University College London.

What will happen next?

The next step will be a telephone call from one of the researchers. If you are interested in participating in the study, they will arrange to visit you at home or see you at the hospital if you already have an appointment booked. This will give you a chance to ask any questions before you make a decision about taking part.

If you do decide to take part you will be given a copy of this information sheet to keep and be asked to sign a consent form.

Who has reviewed the study?

This study has been reviewed and approved by the NRES Committee London – Camden and Islington.

Further information

Or contact the head of the research team: Prof. Anette Schrag at University College at

Email: a.schrag@ucl.ac.uk

Alternatively, you may contact The Dementias and Neurodegeneration Research Network:
General Enquiries, DeNDRoN

27 Old Gloucester Street, LONDON, WC1N 3AX, C/O Box 81.

Phone: +44 (0)20 3206 4960, +44 (0)20 3206 4960

Email: crndementias@nihr.ac.uk

Independent information and advice about taking part in research projects are available from patient advice and liaison Service (PALS) office at the Royal Free NHS Foundation Trust:

Phone: 0207 472 6446 or 0207 472 6447

24-hour answer phone: 0207 472 6445

Text: +447860023323 (Deaf, hard of hearing and hearing impaired patients)

Email: rf.pals@nhs.net

For more information on Parkinson's and how to get involved in other studies, please visit Parkinson's UK's website www.parkinsons.org.uk or NIHR website www.peopleinresearch.org or www.invo.org.uk

Thank you again for reading this information.

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