Validation of the Rater-Administered Psychosis Severity Scale for Parkinson's Disease (Psy-PD)

Patient Information Sheet

Psychosis is common in Parkinson's disease (PD) and occurs in an estimated 20% of PD patients on oral pharmacotherapy. Research from our group and others indicate that psychosis is one of the non-motor symptoms (NMS) with key impact on cognition. It is also known to have a negative effect on the quality of life for both patients and caregivers. Despite this, psychosis continues to be poorly characterised in clinical practice and presents a significant challenge to healthcare professionals dealing with PD.

Precise and effective management of psychosis in PD depends on its recognition, characterisation, and measurement at both the bedside and clinic settings. This study will address the validity of novel modernised PD-specific psychosis severity scale that hopes to capture information about disease-related and drug-induced psychotic symptoms in PD, and how these symptoms evolve. The proposed tool investigates the clinical features of two core aspects of PD psychosis, specifically that of hallucinations and delusions. This scale will be structured in an easy-to-use layout for both the clinician (neurologist/ neuropsychiatrist) and the patient.

<u>What is the purpose of the study?</u>

This study is an educational project. Its purpose is to assist healthcare professionals to be able to characterise and measure psychosis in a reliable way in clinics by providing a comprehensive "one stop" assessment of hallucinations and delusions for patients with PD. It may also assist in determining the effectiveness of certain medications and treatments, as well as empower to patients to describe their psychotic symptoms to clinicians during each appointment.

<u>Who has reviewed the study?</u>

This study has been reviewed and given favourable opinion by xxx Research Ethics Committee. It has also been reviewed by the research officers of the Parkinson's UK charity group, the foremost society championing the cause of Parkinson's in UK. It has also been reviewed by CRISP (Community for Research Involvement and Support for people with

Parkinson's), an expert patient group that reviews research and helps translate current research into treatment.

Do I have to take part?

It is up to you to decide whether you would like to participate, it will not affect the care you receive if you do not. If you do decide to take part then you will be asked to sign a consent form and you will be given a copy of this information sheet.

What will happen if I take part?

Participation in this study will involve the completion of the new psychosis severity scale with a PD specialist. You will be asked questions about psychotic symptoms that might be part of your condition or your treatment. For most people this will take around 45 minutes.

Some patients will also be asked (via telephone) to complete some of the questionnaires again within 7 – 14 days of completing the initial assessment. We anticipate that this re-test will take no more than 15 minutes.

All of the details you provide will be kept confidential. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the routine clinical care you receive. If you decide to withdraw at any stage, all data that has been collected by that time might still be used, but no further data will be collected. Planned treatment will still be received.

How is the data stored?

There will be arrangements made for personal data (email addresses and phone numbers) storage in order for participants to be contacted in the future. They would be stored in e-format on trust laptops secured with password protection. The laptops would be stored in a double-locked cupboard within a secure room. All personally identifiable data would be pseudonymised and hospital-coded. Personal data will only be stored until the recontact is completed (in estimated two weeks' time as per protocol), following which the personal data will be destroyed. The data will be transferred to Spain for advanced statistical analysis by Professor Pablo Martin-Martinez, who is primarily based in Madrid, Spain. Professor Pablo Martin-Martinez is an honorary professor who is a movement disorder specialist at King's College London (KCL)/ King's College Hospital (KCH), and is part of the study team. The transfer of data to Spain would be completed via a secure e-platform which is facilitated by a link on the website. Only study members will have access to this information. The data will then be archived for 5 years as per trust policy.

<u>Who is organising and funding the study?</u>

The sponsor of this study is Kings College London. This study is funded by the National Medical Research Council (NMRC) of Singapore, as part of a fellowship training award.

<u>What are the possible benefits of taking part?</u>

The information we get from this study will help to improve existing clinical assessments to look in depth into any psychotic symptoms and effects of your treatment on symptoms. It will also alert the clinicians to try and treat symptoms which may not have been otherwise declared in clinic, for instance; minor hallucinations and delusions.

<u>What if something goes wrong?</u>

It is unlikely that you will come to any harm from taking part in this study. There are no "interventions such as injections, drugs" etc. as part of the study, apart from the routine clinical care for your Parkinson's. However, if either of you do experience problems there are no special compensation arrangements. If anyone of you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to yourselves: ask to speak to the complaints manager of the hospital. If you have a concern about any aspect of this study you should ask to speak to the researcher who will do their best to answer your questions. If you remain unhappy and wish to complain formally you can contact your local PALS group. Please see contact details below at "contact for further information".

<u>What will happen to the results of the research study?</u>

It is expected that the results of the study will be published in medical journals after the study has been completed but you will not be identified in any report or publication. The results will also be discussed in patient group meetings and international meetings on Parkinson's.

Contact for further information

If you would like any further information please contact:

King's PD Research Team	or	King's Patient Advice and Liaison Service (PALS)
EUROPAR office		Hambledon Wing
King's College Hospital		King's College Hospital
Tel: 020 3299 7154		Tel: 020 3299 3601
Email: kch-tr.PDresearch@nhs.net		Email: kch-tr.pals@nhs.net

This service is available 09:00 -17:00 Monday to Friday.