Imperial College
London

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Participant information sheet: Part 1

Study title
Objective quantification of clinical symptoms of Parkinson's disease through pervasive monitoring

1. Invitation

You are being invited to take part in a research study. Before you decide 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.

This document tells you the purpose of this study and what will your role be if you take part on it. Also, it gives more detailed information about the conduct of the study.

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study.

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

Thank you for reading this.

2. What is the purpose of the study?

In this study we will attempt to measure the severity of certain symptoms that you are experiencing, e.g. how severe your tremor is whilst you are resting. The severity of a particular symptom is rated from 0 to 4 by a clinician during an assessment. The amount of treatment you receive in the form of medication or deep brain stimulation is dependent on the clinician's assessment of your symptoms. How your symptoms are assessed is therefore very important. There have been concerns that the assessments can be subjective, that is the opinion of one clinician on the severity of your symptoms can be quite different to another clinician. Additionally, it might be that the symptoms present during your assessment might not be typical for you. These factors can sometimes affect the amount of treatment you receive. Sensors will be used for the duration of the assessment. The sensors are required to track your physical response throughout the assessment. The data collected in this study will be used to correlate to ratings given by clinicians. The data will also be compared to data obtained from healthy subjects where no symptoms are present. This data may help reduce subjectivity in the future.

Additionally, in the remote assessment part of the study we will attempt to measure how the severity of symptoms you are experiencing change over time. It is known that the severity of your symptoms can change hour-to-hour. Sensors will be sent to you for assessments at home. The data collected will be compared between assessments and used to see if symptom variation can be measured over time. This may help symptom monitoring in the future.

3. Why have I been invited?

You have been invited because you have been diagnosed with Parkinson's disease, are of general good health with healthy limbs, are able to speak English and are able to give informed consent. This study looks at relating data collected from this study to symptoms that you have due to Parkinson's disease. Relating this data will hopefully lead to better scoring of the severity of your symptoms.

4. Do I have to take part?

No - It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Decisions to withdraw at any time, or a decision not to take part, will not affect your future medical care.

5. What is involved in the study?

If you agree to take part in the study, we will ask you to sign a participant consent form using the e-sign.co.uk platform (This platform will record information such as your IP address). At the beginning of the experiment, demographical data including age, duration since onset of disease, gender, current treatment information, length of limb and current symptom scores will be recorded. We will ask you to participate in at least one assessment. This will involve you either (i) sitting comfortably in the chair at a clinic with a team member present (ii) carrying out a selection of normal daily activities at a clinic with a team member present, (iii) sitting at home with the team member guiding your assessment over video call, or (iv) wearing a single device during your normal activity at home. The tests will be of a similar manner to the routine clinical assessment. Your limbs will be observed to measure the amount of tremor (shaking), rigidity (stiffness) and bradykinesia (slow movement) present. The measurement sensors will be attached to your arm. These sensors will allow the research team to hopefully have a better quantification of the severity of your symptoms. One of the measurement sensors will be detached during the assessment. All sensors will be attached externally and connected to a computer.

The sensors that will be used are:

- An inertial measurement sensor connected to the computer via Bluetooth – to measure your movement.
- A force sensor directly connected to the computer – to measure any feedback to the movement.
- A muscle sensor connected to the inertial measurement sensor – to measure the activity of your muscles during the assessment.

A video of the whole assessment will be recorded to gain feedback and further clinical scores from trained clinicians blind to the study, if necessary, at a later stage. This video is optional on your behalf and not required for the study. This will allow the research team to have a more objective opinion on the severity of symptoms. Your face will be blurred out before the video is assessed. The video will not be recorded if you disagree at any point of the assessment to be recorded. Acquired videos will be destroyed if asked to by you at a later stage.

We will ask you to completely relax throughout the whole assessment. The tasks will consist of seven separate tests and each test will be repeated three times with a break in-between. Before you undertake each test you will be given verbal instruction and a physical/video demonstration. The test may involve the clinician, the investigator or your helper moving your arm. You will be given the opportunity to ask questions.

The tasks you may be asked to do during the assessment are:

Test I: Arm rigidity – allow the arm being tested to be as limp as possible. Begin with your arm straight. The clinician/helper will start to move your arm in extension and flexion ten times, after which a ten second break will occur. This will be repeated three times.

Test II: Pronation and supination of hands – hold the arm being assessed out straight in front of you. Rotate your hand as quickly and as far as you can ten times. Have a break for ten seconds. This test will be repeated three times.

Test III: Postural tremor – hold the arm being assessed straight out in front of you. Relax, face your palms downwards, ensure your wrists are straight and your fingers are comfortably spread. Hold this position for ten seconds and then take a break for ten seconds. Repeat this test three times.

Test IV: Kinetic tremor – stretch the arm being assessed straight out in front of you touching the clinician's index finger with your index finger. Now, move your index finger to your nose and back to the clinician's finger. Do this five times. Do not rush the movement. After this has been done five times, have a break for ten seconds. Repeat this three times.

Test V: Rest tremor amplitude – sit quiet in the chair with your arms on the armrest and your feet comfortable on the floor. Stay in this position for ten seconds. Have a break for ten seconds. Repeat this three times.

Test VI: Gait analysis – walk 10 meters away from the starting point given by the clinician and then return to the starting point. Repeat this three times.

Test VII: Rehabilitation exercises – you may be asked to wear the sensors during your standard exercise program.

Activities of Daily Living – once the testing is complete, you may be asked to carry out a selection of common daily activities while wearing the sensors.

Finally, if you wish to participate further in the study, you may be given a PD Track kit take home for up to two weeks. During those two weeks, you will be asked to attend virtual online assessments with the research team to repeat the exercises described above at home. The PD Track software will connect you to the research team via video conference, and they will guide you through the assessments with the PD Track kit virtually. You may also be asked to wear the lower arm device throughout the day when not taking part in a virtual online assessment. After this additional trial period, the research team will arrange for the PD Track to be collected from your home. The cost of delivery will be covered and paid for.

You will be given a rest whenever you want. The virtual online assessment will be video recorded to allow the research team to assess your symptoms. A questionnaire will be given at the end of the assessment for any opinion and feedback you may have about the procedure. This will allow the research team to improve the experience of assessments conducted in the future. The total time required for the setup and the virtual online assessment is 40 minutes.

You may participate in this experiment more than once if you wish.

6. Sites

There are three assessment sites for this study:

- LV Rehabilitation Clinic (Chichester, PO20 3RU).
- SERG Technologies Offices (65D Pall Mall Deposit, London, W10 6BL).
- Imperial College White City Campus (86 Wood Ln, London W12 0BZ).

You will be asked your site preference as you are enrolled onto the study.

6. What is the procedure being tested?

The procedure is being tested to observe whether a more objective approach can better help clinicians when they are assessing your Parkinson's symptoms. The procedure involves measuring your symptoms digitally to assist the clinician in his observations. The sensors described above will look at your movement, your resistance to movement and your muscle activity. These measurements will hopefully correlate to the severity score given by the clinician.

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

The disadvantage of taking part in this study is that it will require time and effort when you may be not feeling motivated to do so. All sensors and systems being used are completely external to your body. All wires will be grounded. If you experience any discomfort or pain in your arm during the test, it will be stopped. This is extremely unlikely to occur. The clinician will be present during the whole virtual online assessment and will be able to advise in discussion with you, whether it is safe to continue the test. If you at any time would prefer to stop the test, it will be stopped immediately.

During the study we will instruct you on the tests you need to perform. The person performing the test will actively move your limb on one test only (Test I). The other tests require effort on your part only. If at any time you are in discomfort during this test, please notify the team and the test will be stopped. The measurement sensors will be attached to you using straps and Velcro. There may be a risk of very slight damage to you skin. However, several procedures have been put in place to ensure no harm comes to you. This includes:

- All sensors have been thoroughly checked to ensure that everything is safe.
- When the sensors are being attached to you, extreme care will be taken.
- All wires will be safely secured to the floor to avoid tripping.
- Constant supervision of your comfort will be made.
- One team member will always oversee you during the whole virtual online assessment.

8. What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. 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 a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Ravi Vaidyanathan - r.vaidyanathan@imperial.ac.uk - +44 (0)20 7594 7020). If you are still not satisfied with the response, you may contact the Imperial College Research Governance Integrity Team (rgitcoordinator@imperial.ac.uk).

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

You are still free to withdraw at any time and without giving a reason. Decisions to withdraw at any time, or a decision not to take part, will not affect your future medical care. If you decide to withdraw from the study and we have already collected some information about you, you have two choices. Either you can let us use the data that we have already collected, or you can ask for it to be destroyed.

10. What are the possible benefits of taking part?

There will be no immediate benefit to you in taking part. However the information gathered in this study may help in the development of a better method in the future for assessing how severe your symptoms are. This study may help clinicians have a better understanding of your symptoms from an objective perspective. This study may result in more efficient and effective treatment.

11. Will any expenses be paid?

Participants will be offered reimbursement as follows: £25 for the first hour, £50 after exceeding two hours, and £100 for an appointment exceeding four hours. A free lunch to participants taking part in the study at a clinic/research site will also be provided.

12. Contingency plan for injuries

There are no injuries related to this experiment likely to take place. Any injury unrelated and/or indirectly related to the execution of the experiment will be managed with the maximum possible care and attention. First aid kits are available at the testing sites where the experiment takes place. A telephone indicating the (internal and external) numbers to call in case of emergency is available at the testing sites.

13. Will my taking part in the study be kept confidential?

All information which is collected about participants during the course of the research will be kept strictly confidential. All information collected will not identify you and will not be combined with other information in a way that could identify you. It will not be used to make decisions about future services available to you, such as insurance. The collected information will be used for the purposes of this project only and will not be redistributed for any other purpose. Only the investigators will have access to the data, which will be stored with security protection (passwords) for 10 years after the completion of the project to allow for publication revisions and further analysis of the data. Further information on Imperial College London's retention periods may be found at https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf.

14. What will happen to the results of the research study?

The research team will not provide any feedback on individual results obtained during this study. If you would like to know the general findings of the study, you can do so by contacting Ravi Vaidyanathan by email at r.vaidyanathan@imperial.ac.uk.

15. Who is organising and funding the research?

This research is being led by the Biomechatronics Lab at Imperial College London. Our team includes members from Imperial College London, St George's University Hospital, the LV Clinic and SERG Technologies.

16. Who has reviewed the study?

The College and those conducting this research study subscribe to the ethical conduct of research and to the protection at all times of the interests, comfort, and safety of participants. This research is being conducted under permission of the Research Governance and Integrity Team (RGIT).

17. Contact for Further Information

If you would like any further information, you can request it by contacting Ravi Vaidyanathan by email at r.vaidyanathan@imperial.ac.uk.

Participant information sheet: Part 2

Transparency notice

Imperial College London 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. Imperial College London. will keep identifiable information about you.

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

Further information on Imperial College London's retention periods may be found at https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf.

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 information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information, please contact:

Principal Investigator:
Ravi Vaidyanathan
Email: r.vaidyanathan@imperial.ac.uk
Telephone: +44 (0)2075947020

Imperial College London will collect information from you for this research study in accordance with our instructions.

Imperial College London will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. The only people in Imperial College who will have access to information that identifies you will be people who need to contact you to conduct the research or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Imperial College London will keep identifiable information about you from this study for 10 years after the study has finished.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in any aspect of health or care and could be combined with information about you from other sources held by researchers, or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.
Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
- The following Research Collaborators / Partners in the study;
    - LV Clinic – The LV Clinic will be one of the testing site and will hold personal information for the purposes of scheduling appointments. They will also have access to data recorded as they provide input and feedback to the algorithms being developed during this study.
    - St George's University Hospital – Team members from St George's University Hospital will review data collected for the purpose of system development and improvement. This information will not be stored at the hospital site, or on any NHS system.
    - SERG Technologies – SERG Technologies are developing the hardware and software used in these experiments. They will use data collected to arrange

assessments, as well as the testing and modification of the system. SERG Technologies will also be one of the testing sites and will hold personal information for the purpose of scheduling appointments.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason. At this time, you may request for any identifying data held as part of the study to be deleted.

- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. We will ask you to confirm whether you would like to be contacted regarding future research at the culmination of this study.

Where can you find out more about how your information is used?
You can find out more about how we use your information:

- by asking one of the research team.
- by sending an email to Ravi Vaidyanathan at r.vaidyanathan@imperial.ac.uk.

CONTACT US

If you wish to raise a complaint on how we have handled your personal data or if you want to find out more about how we use your information, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

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 Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.