Transforming Parkinson's Care in Africa (TraPCAf)

Participant Information Sheet and Consent Form:

Technology for Parkinson's disease

Part 1: Participant Information Sheet

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others, but it is up to you to decide whether to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

This research is about a condition called Parkinson's disease. Parkinson's disease affects the brain. It involves symptoms such as shaking, slow movement and stiffness that get worse over time. Parkinson's disease can have a big impact on someone's life, and it is important for it to be identified and managed early. Parkinson's disease is diagnosed mainly through clinical examination and ideally by a doctor who specialises in Parkinson's disease, often this is a neurologist. Once someone is diagnosed, they can begin to access treatment and care to manage the symptoms.

This aspect of the study is part of a bigger research study taking place across Africa to understand more about Parkinson's disease. The research, called Transforming Parkinson's Care in Africa (TraPCAf), is funded by the National Institute for Health and Care Research (NIHR) in the UK. This part of the study involves using technology to diagnose, monitor and manage symptoms of Parkinson's disease and the progression of the disease. Technology has the potential to help people with Parkinson's disease.

Why have I been asked to participate?

You are being asked to take part in this research because you have been diagnosed with Parkinson's disease, you are under the care of a neurologist who is participating in the wider research study, and you consented to being approached by the research team to take part in this aspect of the study.

What will happen to me if I take part?

You will be invited to a neurology clinic and would have to come into the clinic. The researcher would help you set up the technology and explain how to use it. There are various different tools and mobile phone apps that we can use to help diagnose and monitor Parkinson's disease, outlined here:

- **Smart watch (CUE BAND wristwatch and smartphone application)**

  People with Parkinson's disease may experience excessive drooling because they do not swallow as much saliva. This can to problems in the future. We are testing the use of both a wearable smart watch and a smartphone application which gives you regular reminders to swallow through vibration and sound. This part of the study would last for 8 weeks. For the first 2 weeks, without any devices you will keep a diary of your drooling symptoms. You will then be testing both the smart watch, which we will give to you, and smartphone application separately, each for 3

weeks. You will be able to keep the smart watch (CUE BAND) after the study has been completed.

To take part in this aspect of the study, you would need to have a smartphone that was compatible with the smart watch.

- **Smart pen (NeuroMotorPen)**

  This is a specially designed digital smart pen that is used on a flat tablet screen. This includes copying shapes like a circle or letters and writing. We can analyse your drawing and writing pattern using this smart pen to help determine if you have Parkinson's disease. This could be used to help diagnose Parkinson's disease in the future.

  To take part in this aspect of the study, you would have to complete these tests in the clinic.

- **Smartphone application (Oxford app)**

  This is a smartphone application which tests movement function of the body including tremors, finger tapping, and balance. Information collected can be assessed remotely by a specialist to help diagnose Parkinson's disease or monitor progression. The app will ask you specific questions and to perform certain tasks through your smartphone for about 6 minutes. Once complete, your results will be shared securely with the team and analysed.

  To take part in this aspect of the study, you would need to have a smartphone that was compatible with the app.

- **Gait monitoring – Ghana only**

  Walking whilst attached to a special sensor can help us study your walking patterns and identify early signs of Parkinson's disease, monitor its progression and check response to treatment. You will be provided with a non-invasive device (Axivity AX6 sensor) which will be placed on your lower back for continuous real-world monitoring of your walking. It will detect your live movement, acceleration and body position. Once completed, the device can be taken off.

  To take part in this aspect of the study, you have to be able to walk at least 10 metres without any aid. You would need to come to the clinic to be fitted with the device, then wear the device at home for a period of time.

- **OCT eye test (Optical Coherence Tomography)**

  It is possible to use a special portable eye test device to take pictures of the back of your eyes. It is a quick, non-invasive test that can detect changes in the structure of the retina, which can be affected with conditions like Parkinson's disease. It uses infrared technology, with no eye drops required.

  To take in this aspect of the study, you would have to come in to the clinic to have the eye test.

What are the benefits in my taking part?

By taking part in this study, you will play an important role in helping research discover new ways to identify and manage Parkinson's disease that will be used across the world.

Are there any risks involved?

There are no risks to you using these technologies. If you experience any difficulties with any of the take home technology, let us know.

What data will be collected?

We will collect data about your symptoms and movement related to the technology you opt in to try.

Will my participation be confidential?

Your participation will be confidential, and all data collected about you will be confidential. Your data will be anonymised (this means that we will allocate a code to your information, instead of your name, so that no one can identify you). All data will be stored on password protected computers and only members of the clinical and research team will have access to it. The consent form you sign will be locked away in a safe. Data about you will be stored securely for 10 years after the end of the study and then deleted.

Do I have to take part?

Participation in this part of the study is voluntary and you are free to decline to be in this study or change your mind at any point. You do not have to decide now if you want to participate, you can think about it and discuss it with your family. If you have any questions, you can contact the researcher.

If you change your mind about taking part, just let us know. You can withdraw your data and information even after the data has been collected.

What will happen to the results of the research?

The goal of this research is to understand more about Parkinson's disease in Africa, to help develop ways to easily diagnose Parkinson's disease and monitor disease symptoms and progression. All the data we collect will be anonymised, stored and analysed by the researchers. This data, along with the data we collect as part of the wider research study, will be published in academic journals and be fed back to policy makers to advocate for better care and support for people with Parkinson's disease.

Where can I get more information?

If you want to discuss this study further, please get in touch with the research team:

Contact name:

Phone number:

This study was approved by the Faculty of Medical Sciences Research Ethics Committee, part of Newcastle University's Research Ethics Committee. This committee contains members who are internal to the Faculty. This study was reviewed by members of the committee, who must provide impartial advice and avoid significant conflicts of interests.

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Part 2: Consent form

Participant consent

I have been invited to take part in this research study about Parkinson's disease. I have been given and read the information sheet, or the information sheet has been read to me. I have had the opportunity to ask questions about it and any questions have been answered to my satisfaction. I understand my participation is voluntary and I may withdraw (at any time) for any reason without my participation rights being affected. I have consented voluntarily to be a participant in this study and agree for my data to be used for the purpose of this study outlined in the information sheet.

I would like to take part in this study and consent to (initial the boxes):

Smart watch and application to help with drooling (CUE BAND)	
Smart pen to diagnose Parkinson's (NeuroMotorPen)	
Smartphone application to monitor movement (Oxford app)	
Device to monitor gait (Ghana only)	
OCT eye test to check for changes in the retina	

Name of participant:

Signature/Initials: **Thumbprint:**

Date:

For researcher

To the best of my ability, I have provided the information sheet, and accurately read out the information sheet to the potential participant, if necessary. I have ensured that the participant understands the details of the study. I confirm that the participant was given an opportunity to ask questions about the study, and these were answered correctly to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this Participant Information Sheet has been provided to the participant.

Name of researcher:

Signature:

Date:

For interpreter (if present)

I can confirm that the information I have translated today will not be shared with anyone and the participant will not be made identifiable. I have read the information sheet and confirm that the confidentiality of the participant will be ensured at all times.

Name of interpreter:

Signature:

Date: