Transforming Parkinson's Care in Africa (TraPCAf)

Participant Information Sheet and Consent Form:

Neurology assessment

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 identifying people with Parkinson's disease in the community.

Why have I been asked to participate?

You are being asked to take part in this research because you answered positively to one or more of the screening questions that you were asked during a recent census visit at your home. These screening questions suggest that you might have Parkinson's disease. We would like to invite you to come to the local neurology clinical to undergo a full neurology assessment by a specialist doctor. This will allow us to tell you whether you have Parkinson's disease or not.

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 for the assessment. The neurologist will ask you some questions about your medical history and ask you to do some simple movement exercises (e.g., ask you to walk, or ask you to tap your fingers together). The neurologist will then be able to determine if you have Parkinson's disease.

If you have paid for transport to the clinic, this will be refunded by the research team.

What are the benefits in my taking part?

By the end of the assessment, the neurologist will be able to tell you whether you have Parkinson’s disease or not. If you do have Parkinson’s disease, you will be able to start on medication that will help to manage your symptoms and you may be able to access other support, for example, a physiotherapist who can help you with your movement, or a patient support group. You will also be invited to take part in further research on Parkinson’s disease, which the researcher will explain.

You may be diagnosed with another medical condition, which may require further investigations and treatment, and the research team will direct you to where you can receive help.

Are there any risks involved?

There are no risks to you being involved in this clinical assessment. You will be able to ask the neurologist and researchers about the disease if you have any questions about your diagnosis.

What data will be collected?

We will collect data about your medical history, any medication you take and information about any symptoms you experience, which will be used to determine whether you have Parkinson’s disease or not.

Will my participation be confidential?

Your participation will be confidential and all data collected about you will be confidential. The neurologist who assesses you will be bound by doctor-patient confidentiality. For the purposes of the research study, your data will be anonymised (this means that we will allocate a code to your information 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 assessment.

What will happen to the results of the research?

The goal of this research is to understand more about Parkinson’s disease in Africa. 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.

Name of participant:

Signature/Initials: **Thumbprint:** ☐

Date:

Please put your initials in the box below if you agree with the statement:

☐ If I am diagnosed with Parkinson's disease, I consent to the research team inviting me to participate in further research.

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: