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Transforming Parkinson's care in Africa

Submission date
23/03/2023

Recruitment status
No longer recruiting

Registration date
13/04/2023

Overall study status
Completed

Last Edited
15/10/2026

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is the second most common neurodegenerative disease worldwide and is becoming an increasing problem in Africa primarily due to ageing and growing populations. We know there is a lack of trained specialist staff to manage the disease and also limited community awareness about PD, all of which results in many people remaining undiagnosed. Even those who are diagnosed have a major challenge in identifying affordable, locally available and sustainable drug treatment, with challenging access to specialist follow up and support. Overall, our aim is to describe and gain a better understanding of the current situation of PD in 7 countries in Africa (Egypt, Ethiopia, Ghana, Kenya, Nigeria, South Africa and Tanzania).

Who can participate?
This study is about Parkinson’s disease. All people with PD diagnosed at the participating clinical sites will be invited to take part in the study. We are also doing a community door-to-door study in four sites, so anyone we identify during this part of the study will be invited to take part. We will also invite healthy individuals to act as controls for some parts of the study.

What does the study involve?
We plan to investigate the burden of PD, determine risk factors for developing PD and explore the genetics of PD. We will measure how people respond to drug treatment, trial an alternative treatment with a bean called Mucuna Pruriens, and investigate ways to improve diagnosis. We will build research and clinical capacity in all countries, considering lack of access to specialists, explore people’s lived experience of the disease, all the while with the engagement and support of the community.

What are the possible benefits and risks of participating?
There are no direct benefits to the participants, except for a better understanding of disease. All participants will be invited to join a local support group to gain further information and meet others with PD. The only risks relate to collecting biological specimens, for example, taking blood, but this should not pose a great risk. There may be some minor side effects experienced by people involved in the trial of Mucuna Pruriens, such as mild nausea. If this happens, they will be able to withdraw from the study and the nausea will stop immediately.

Where is the study run from?
The study is being run from Newcastle University in the UK, but there are several sites involved in the conduct of the research.

When is the study starting and how long is it expected to run for?
The study began in September 2022 and is expected to run until August 2026.

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR) Global Health Research Programme in the UK.

Who is the main contact?
Professor Richard Walker, richard.walker@nhct.nhs.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Richard Walker

ORCID ID
https://orcid.org/0000-0003-3155-122X

Contact details
Department of Medicine
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH
+44 191 2932709
richard.walker@nhct.nhs.uk

Type(s)
Scientific

Contact name
Prof Njideka Okubadejo

ORCID ID
https://orcid.org/0000-0003-2975-8803

Contact details
College of Medicine
University of Lagos & Lagos University Teaching Hospital
Idi Araba
Lagos State
Lagos
Nigeria

102215
+234 812 836 4824
nokubadejo@unilag.edu.ng

Type(s)
Scientific

Contact name
Miss Mia Porteous

Contact details
Faculty of Medical Sciences
Wolfson Building , G20
Medical School
Framlington Place
Newcastle upon Tyne
United Kingdom
NE2 4HH
+44 (0)191 208 7850
trapcaf@newcastle.ac.uk

Additional identifiers

National Institute for Health and Care Research (NIHR)
133391

Study information

Scientific Title
Global health research group on transforming Parkinson's care in Africa

Acronym
TraPCAf

Study objectives
Parkinson's disease (PD) is the fastest growing neurological disorder in terms of the number of people affected and the attributable disability. As global populations continue to increase over the coming decades, the burden of PD as a neurodegenerative disease predominantly affecting the ageing is projected to continue to rise. Improving life expectancy and the sheer numbers of people in Africa above the age of 60 years are indications that the population at risk of PD will increase significantly across Africa in the future. Given this scenario, and the relative paucity of data on the epidemiology (including risk factors - genetic and environmental), clinical profile, treatment, outcomes, and impact of PD on people with PD, their caregivers and families, studies addressing PD across Africa are warranted. This will enable a better understanding of how PD affects people in Africa, and provide data to guide policy development, change and implementation. The NIHR funded TraPCAf study is a multi-faceted, multi-country study spanning 7 work packages, including a prevalence studies, observational studies, interventions, a clinical trial, explorative qualitative work and other epidemiological (environmental risk assessment) studies. The goal of the study is to transform Parkinson's diagnosis, treatment and care in the 7 countries included in the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/02/2023, Faculty of Medical Sciences Research Ethics Committee, Newcastle University Research Ethics Committee (Faculty of Medical Sciences, Newcastle University, Framlington Place, Newcastle upon Tyne NE2 4HH, UK; +44 191 208 6000; fmsethics@ncl.ac.uk), ref: 2023 2453/26903/2021
Approval has also either been received or is in processing at all sites involved in the 7 countries.

Primary study design
Other

Study design
The multi-country, multi-centre study uses a dual design combining observational (qualitative and quantitative approaches for the epidemiological, clinical, risk factor, lived experiences components, as appropriate) and interventional (clinical trial component) methods. The interventional component is a double-blind randomized controlled trial. The observational components use a cross-sectional cohort design.

Study type(s)
Other

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
Participants will be persons living with Parkinson’s disease (PD) and healthy unrelated volunteers (controls). In addition, caregivers of people with PD (PwP) will participate alongside the PwP for the qualitative studies.
In brief, during the community-based prevalence studies, door-to-door surveys will be conducted in designated and census-delineated communities in the 4 countries included in the prevalence studies work package. Adults aged 18 years and above resident in the survey site for at least 12 months preceding and including the prevalence day will be surveyed using a short questionnaire designed to screen for symptoms of parkinsonism. Persons screening positive will undergo a second in-person evaluation with a neurologist or movement disorders specialist to validate the clinical diagnosis of parkinsonism and Parkinson’s disease using the UKPDSBB criteria. A sample of persons screening negative will also undergo an in-person evaluation to exclude parkinsonism. The data will be utilized to assess the performance of the survey instrument.
In addition, for the environmental risk assessment component in the community, soil and water samples will be collected using conventional techniques for toxicology assessment. All PwP from the prevalence studies and PwP at all participating hospitals (consecutively attending consenting to participate), will have a study-related in-person assessment including: documentation of PD-related historical data, diagnostic ascertainment, phenotypic characterization of disease stage and severity and motor and non-motor features, and quality of life (MDS UPDRS, MDS NMSQ, Barthel ADL scale, PDQ, RBDQ, SCOPA-AUT, IDEA, MoCA, QUIP, etc), and environmental risk factor assessment using the MERQ-PD.
With consent, biological samples will be collected for metabolomics (sebum samples via swab stick), gut microbiome (stool and saliva/oral swabs), urine and serum samples (for PD diagnosis using extracellular synucleinopathic protein assay based on fluorescent dye technique) and genomics studies (blood/saliva for DNA extraction and genotyping using the PD-specific

NeuroChip® genotyping platform). Clinic-based PwP will also be requested to provide water and soil samples from their place of residence.
Paired caregiver and PwP teams will undergo an in-person interview (together or separately) to understand the lived experiences of PD. Healthy volunteer controls will undergo an abridged version of the assessments (baseline demographics, abridged neurological examination, minimum dataset of cognition and other non-motor features, environmental risk factor questionnaire, and biological samples). In some sites, additional assessments including gait assessment and wearable technology assessments and optical computerized tomography (OCT) will be conducted in a proportion of participants, with consent. In addition, the performance /utility of specified diagnostic aids for differentiating PD from healthy persons and/or promoting earlier diagnosis of PD and improving treatment will be assessed in a subset of participants using the following non-invasive instruments: assessment of wearable technology for gait assessment, Neuromotor Pen® for assessment of bradykinesia and tremor, and OCT (retinal scans) to distinguish PD from controls. The CUE-BAND® wrist worn device for prompting /cueing in the management of drooling will be tested.

Data collection is cross-sectional and will require approximately 2 hours of participation. For the clinical trial on Mucuna pruriens, the study adopts a phase II proof-of-concept, double-blind randomized controlled non-inferiority design, and will enrol about 90 participants in 2 pre-specified sites, allocating the treatment naïve PwP to either receive Mucuna pruriens or equivalent dose levodopa/carbidopa. The duration of the clinical trial will be 12 months. Analysis will be by intention to treat. For all PwP, a follow-up assessment of disease progression (assessment of motor and non-motor features and cognition) will occur one year after the initial assessment during routine clinic follow-up visits.

Intervention Type
Mixed

Primary outcome(s)
1. Prevalence study: Prevalence of PD will be measured using the community-based parkinsonism screening interview and second stage physician verified diagnosis of PD and reported as Number of persons with PD per 100,000 population. Data will be age-adjusted to the WHO World population.
2. Environmental risk factor assessments: Environmental risk factors for PD will be measured at baseline using (i) toxicology assessment for contaminants of emerging concern related to PD (including pesticides, herbicides, other chemicals and heavy metals) in the soil and water samples at residences of PwP versus healthy volunteers and (ii) Comparison of the risk exposures of PwP and controls based on responses in the NINDS CDE MERQ and PD RFQ questionnaires and reported as the relative risk of exposure for each subcategory of risk factors interrogated.
3. Metabolome studies (conducted at baseline) primary outcome will be the diagnostic utility of skin metabolites measured in sebum in differentiating PwP from controls.
4. Microbiome studies (conducted at baseline) primary outcome will be the differences in the gut and oral microbiome composition in PwP and controls measured using microbiota data on alpha diversity, beta diversity, differential abundance of microbial taxa and functional gene analysis in PwP compared to controls.
5. Mucuna pruriens clinical trial: the primary outcome will be the efficacy of M. pruriens compared to levodopa/carbidopa measured by degree of change in the MDS-UPDRS Motor (Part III) scores at baseline (time point 0 i.e. treatment naive compared to 12 months on treatment.
6. Diagnostic aids and Treatment aids: The primary outcome measure of these devices/aids will be the diagnostic utility and/or performance in PwP (compared to controls where relevant). The

diagnostic aids and treatment aids related to this outcome and the measures relevant to them are as follows: Gait (wearable technology for measuring gait in PD), Neuromotor Pen ® (diagnosis of bradykinesia and tremor), optical coherence tomography (retinal changes in PD), CUE BAND ® wrist worn device (cues and prompts for sialorrhea).
7. Genomics studies: the primary outcome will be the Odds ratio (or Hazards ratio) of specified single nucleotide polymorphisms (SNPs) measured as the frequency of polymorphic variation in pwPD versus controls (based on the genotyping results from the NeuroChip ® platform. Genome-wide analysis data comparing PD and controls will also be reported as an outcome.

Key secondary outcome(s)
1. Phenotypic characterization of Parkinson's disease will be assessed at baseline using the validated measures described in the methodology, including the MDS-UPDRS (PD severity and stage), Cognitive function (MoCA and IDEA), non-motor symptoms burden (MDS NMSQ), quality of life (PDQ8), REM sleep behavioural disorder (RBDQ), autonomic symptomatology (SCOPA-AUT), and reported as secondary outcomes (frequency of phenotypic characteristics, motor phenotype of PD, frequency of cognitive dysfunction, autonomic dysfunction, impulsivity, hyposmia, REM sleep behavioural disorder), health-related QOL (PDQ 8 summary scores and derivation) and Barthel activities of daily living (ADL) scale (summary scores).
2. Cost effectiveness of Mucuna pruriens as a treatment for PD in Africa (comparative analysis versus cost of equivalent dose of levodopa therapy) over a 12-month period

Completion date
31/08/2026

Eligibility

Key inclusion criteria
A. Prevalence study:
1. Participant resident in the delineated community for at least 12 months prior to the date of survey
2. Age 18 years or older

B. Other clinical studies (including clinical trial): Persons with PD
1. Participant diagnosed with PD based on UKPD brain bank clinical criteria
2. Age 18 years or older
3. Consent to participate obtained
4. Any stage of PD
5. Either treatment naive (only for mucuna prurens trial) or on treatment (any study component)

B. Healthy control:
1. Neurologically normal (assessed at in-person physical examination)
2. Age 18 years or older
3. Consent to participate

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Non consent/lacking capacity
2. Physically unable to complete study procedures due to advanced disease and physical disability

Date of first enrolment
01/05/2023

Date of final enrolment
31/05/2026

Locations

Countries of recruitment
Egypt

Ethiopia

Ghana

Kenya

Nigeria

South Africa

Tanzania

Study participating centre
KEMRI Wellcome Trust
Hospital Rd, Kilifi
Kilifi
Kenya
P.O Box 230

Study participating centre
Ain Shams University Hospital
El-Khalyfa El-Mamoun Street Abbasya, Cairo , Eygpt
Cairo
Egypt
11588

Study participating centre
Tikur Anbessa Specialised Hospital
Addis Ababa
Ethiopia
P.O.Box 5657

Study participating centre
Korle Bu Teaching Hospital
22nd Guggisberg Ave, Accra, Ghana
Accra
Ghana
P. O. Box 77

Study participating centre
Komfo Anokye Teaching Hospital
Okomfo Anokye Road, Kumasi, Ghana
Kumasi
Ghana
P.O.Box 1934

Study participating centre
Richard Novati Catholic Hospital
Sogakope
Ghana
P. O. Box SD 95

Study participating centre
Lagos University Teaching Hospital
Ishaga Rd, Idi-Araba 102215, Lagos, Nigeria
Lagos
Nigeria
102215

Study participating centre
Inkosi Albert Luthuli Central Hospital
800 Vusi Mzimela Rd, Umkumbaan, Durban, South Africa
Durban
South Africa
4091

Study participating centre
Kilimanjaro Christian Medical Centre
Moshi
Tanzania
PO Box 3010

Study participating centre
Muhimbili Mloganzila Hospital
Dar es Salaam
Tanzania
65000

Study participating centre
Aga Khan University Nairobi
3rd Parklands Ave
Nairobi
Kenya
PO Box 30270-00100

Sponsor information

Organisation
Newcastle University

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type

Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/10/2023	20/10/2023	Yes	No
Participant information sheet	PIS - TraPCAf and GP2		06/04/2023	No	Yes
Participant information sheet	PIS and consent form - HCP and policy maker interview		06/04/2023	No	Yes
Participant information sheet	PIS and consent form - PwP interview		06/04/2023	No	Yes
Participant information sheet	PIS and consent form - caregiver interview		06/04/2023	No	Yes
Participant information sheet	PIS and consent form - examination and samples		06/04/2023	No	Yes
Participant information sheet	PIS and consent form - neurology assessment		06/04/2023	No	Yes
Participant information sheet	PIS and consent form - prevalence community visit		06/04/2023	No	Yes
Participant information sheet	PIS and consent form - technology		06/04/2023	No	Yes