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PRIME Parkinson: a cross-sectional study of patients with parkinsonism in the Bath area and their caregivers

Submission date
04/11/2020

Recruitment status
No longer recruiting

Registration date
15/12/2020

Overall study status
Completed

Last Edited
08/04/2025

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is known that having Parkinson's disease (PD) can have a negative impact on the quality of life. People with PD may experience other health problems such as depression, memory problems, or bladder issues, and are also more likely to be admitted to hospital than people without PD. As PD progresses, many people will need the help of a caregiver. Often this care is provided by friends or family members who are not paid for the care and support they give. Being a caregiver can be stressful and put a strain on the caregiver's own physical and mental health.

This study aims to further understand the needs of people with PD (and other related conditions such as Lewy body dementia), who are cared for by a specialist at the Royal United Hospital in Bath, in terms of their stage of the disease, what symptoms bother them and what other health problems they experience alongside their PD. The help which people with PD receive, particularly from unpaid caregivers, such as family and friends will be investigated. Information about the experiences of unpaid caregivers will also be collected, how caring impacts their quality of life, and what strategies they use to cope with their role.

It is important to understand the needs of people with PD and their caregivers, including people with PD who have generally been excluded from previous studies, so that better ways to look after these groups can be developed. In the future, the information from this study will be used to help design and test out a future research study about caring for people with PD and supporting caregivers of people with PD.

Who can participate?
Adult PD patients and unpaid caregivers who provide informal care or support for a patient with PD and are considered by the patient to be their primary caregiver.

What does the study involve?
Participants in this study will be asked to complete questionnaires on one occasion only. These questionnaires will collect information on the stage of the participants' disease, what symptoms bother them, and what other health problems they experience alongside their PD. Caregivers

will be asked about their experiences of unpaid caregiving, how caring impacts their quality of life, and what strategies they use to cope with their role.

What are the possible benefits and risks of participating?
The participants who have Parkinson's disease continue with their usual care and treatment via their Parkinson's team and so the anticipated risks of the study are minimal. The researchers acknowledge that questionnaire completion can be burdensome for people with Parkinson's and those who support or care for them and have taken all possible steps to make completion as easy as possible for participants.
Acknowledging that this is a potentially vulnerable group of individuals and that questionnaire completion may raise concerns or issues for a few patients or caregivers, the researchers have taken steps to provide as much support as possible to support participants. They can support participants to complete over the telephone if they would like this. Participants will be advised that they can contact the PRIME Parkinson team to discuss any concerns or emotions raised by completing the questionnaires and contact details are provided at the end of the questionnaire booklets and in the Participant Information Booklets. The study team will signpost on appropriately if they are unable to resolve the matter directly. Patient participants will also be advised to discuss their concerns with the healthcare professional who manages their parkinsonism. The caregiver and consultee information booklets also contain contact details for local caregiver support agencies and charities.

Where is the study run from?
Royal United Hospitals Bath NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2018 to February 2025

Who is funding the study?
The Gatsby Charitable Foundation (grant code: GAT3676) (UK)

Who is the main contact?
Charlotte McDonald
prime-parkinson@bristol.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Charlotte McDonald

Contact details
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
285041

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 46213, IRAS 285041

Study information

Scientific Title
Prime Parkinson cross-sectional study

Acronym
PRIME Parkinson

Study objectives
This cross-sectional study has been designed to describe the population of people with Parkinson's disease (and related conditions) who are under the care of a neurologist or geriatrician at Royal United Hospitals (RUH) Bath NHS Foundation Trust, UK. It also aims to describe the characteristics and experiences of those who care for or support someone with Parkinson's. Understanding the characteristics of these individuals is crucial to designing better services to meet their needs in future.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/07/2020, London- Brighton & Sussex REC (Health Research Authority, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)207 104 8241; brightonandsussex.rec@hra.nhs.uk), ref: 20/LO/0890

Study design
Observational cross-sectional study

Primary study design
Observational

Study type(s)
Other

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

Interventions
This is a cross-sectional study designed to describe the variability in stage and needs of people with parkinsonism in the catchment area of the Royal United Hospitals Bath NHS Foundation Trust, UK, along with the experiences of their caregivers, using questionnaires. Each participant will be invited to complete one questionnaire booklet on one occasion.

People with parkinsonism, along with the people who provide care or support them, will be invited to take part. Patient participants will be drawn from clinical lists of those who are looked after by a geriatrician or neurologist at the Royal United Hospitals Bath NHS Foundation Trust, UK.

Written informed consent will be sought from all participants. In the case of participants who are unable to provide informed consent, the clinical team will seek advice from a close family or friend (acting as their personal consultee) who will be asked to complete a consultee declaration form, the shorter patient questionnaire booklet for completion by a representative will be sent to the family member or friend who has agreed to complete the questionnaires on their behalf. The person fulfilling this role is referred to as the 'representative').

There are three questionnaire booklets in use in the study:
1) A full patient questionnaire booklet for individuals who can provide informed consent and are able to provide answers to the questions.
2) A shorter patient questionnaire booklet for completion by a representative of the patient (who is likely to have also acted as the personal consultee), if the person with Parkinson's is unable to provide informed consent and cannot answer the questions themselves.
3) A caregiver questionnaire booklet

Completion of the questionnaire booklet can be facilitated by a researcher asking the questions over the telephone or face-to-face in the participant's own home. Questionnaire booklets can be completed over a number of days at the participants' convenience. Patient participants may have assistance to document their answers from a friend or family member, so long as the answers are their own. Patient participants may take part in the study even if they have a caregiver who does not wish to do so; similarly a caregiver may take part even if the person for whom they provide support or care is not participating in the study.

All three questionnaire booklets contain the contact details of the study team and participants are advised that they can call to speak to the team if any concerns or emotions have arisen during questionnaire completion. The study team will signpost on if needed. The clinical team will continue to identify people who are newly diagnosed as having Parkinson's, or a related condition, who are eligible to take part in the study, as well as the people who help or support them. These individuals can be invited to participate if they are confirmed to have Parkinson's disease within the 12 month period of the study.

Intervention Type
Other

Primary outcome(s)
1. Patient participants: quality of life measured by the Parkinson's Disease Questionnaire-39 at a single timepoint
2. Patient participant (representative-completed): quality of life/wellbeing measured by the ICEpop CAPability measure for Older people, proxy version (ICECAP-O proxy) at a single timepoint

3. Caregiver participants: quality of life measured by the Parkinson's Disease Questionnaire-carer at a single timepoint

Key secondary outcome(s))
1. Patient participants: non-motor symptom score measured by the Non-Motor Symptom Questionnaire (NMSQ) at a single timepoint
2. Patient participants: (representative completed): neuropsychiatric symptoms measured using the Neuropsychiatric Inventory Questionnaire (NPI-Q) at a single timepoint
3. Caregiver participants: caregiver burden measured using the Zarit Burden Inventory at a single timepoint

Completion date
28/02/2025

Eligibility

Key inclusion criteria
Patient participants:
1. Diagnosis of parkinsonism (including idiopathic Parkinson’s disease, progressive supranuclear palsy, corticobasal degeneration, multisystem atrophy, dementia with Lewy bodies, vascular parkinsonism), made by a movement disorder specialist
2. Willing to participate and have the ability to provide informed consent to participate or, where unable to do so due to cognitive impairment, availability of a close friend, or relative to act as a personal consultee.
3. Aged > 18 years

Caregiver participants:
1. Provide informal care or support for a patient with parkinsonism and, where a patient has more than one informal caregiver, be considered by the patient to be their primary caregiver
2. Willing to participate and have the ability to provide informed consent to participate
3. Aged >18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
918

Key exclusion criteria
Patient participants:
1. Drug-induced parkinsonism
2. Lack capacity to consent to participate and do not have anyone who can be a consultee to provide advice regarding the patient's wishes and views.
3. Current medical, cognitive or psychosocial issue or co-enrolment in other studies that, in the opinion of the investigators, would interfere with adherence to study requirements.

Caregiver participants:
1. Professional carers who are paid to deliver care

Date of first enrolment
24/09/2020

Date of final enrolment
02/09/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
Gatsby Charitable Foundation

Alternative Name(s)
GATSBY, The Gatsby Charitable Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the PRIME programme manager, Charlotte McDonald, via the PRIME mailbox (prime-parkinson@bristol.ac.uk), following completion of all data collection. The participant consent form included consent to share pseudo-anonymised data with researchers in other organisations.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2024	25/03/2025	Yes	No
Protocol article		11/05/2022	12/05/2022	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results		31/03/2025	07/04/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes