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Proactive and integrated management and empowerment in Parkinson's disease (PRIME-PD): designing a new model of care

Submission date
21/02/2022

Recruitment status
No longer recruiting

Registration date
04/03/2022

Overall study status
Completed

Last Edited
08/04/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
This trial is called the PRIME Parkinson Randomised Controlled Trial (RCT).
Parkinson's disease is a condition in which parts of the brain become progressively damaged over many years leading to shaking, stiffness, and difficulty with walking, balance, and coordination.
Current models of care are not optimised for people with Parkinson's and the wide range of symptoms and different experiences they may encounter. Current care can be slow to react to changes in symptoms, communication between different healthcare providers can be problematic, and including patients in optimal decision-making based on their unique circumstances is challenging.
This trial aims to find out whether a new model of care, termed "PRIME Parkinson Care" is helpful for people living with Parkinson's. We want to ascertain whether this new model can support people to live well with Parkinson's. This trial compares a new additional model of care operating in tandem with their usual care provided by the UK National Health Service (NHS), against usual care on its own.

Who can participate?
We are inviting people with Parkinson's and similar conditions, such as corticobasal degeneration, Lewy Body dementia, and vascular parkinsonism. However, people with drug-induced parkinsonism are ineligible and therefore excluded.
In addition to having Parkinson's, you need to be:
· Over the age of 18 years
· Willing to take part
· Live in the catchment area of the RUH Bath
Additionally, they must also be able to provide informed consent, or where unable to do so due to cognitive impairment, have the availability of a close friend or relative to act as a personal consultee. Patients who lack capacity but do not have someone to act as their personal consultee, unfortunately, cannot take part.

What does the study involve?
People taking part in the trial will be allocated to be in either group A or group B, with an equal chance of being allocated to either. The groups are chosen at random by a computer system, and participants will know which group they are in.
In group A, participants will receive exactly the same care as they would if they were not in the trial. The only difference will be that they will be asked to complete some questionnaires and speak to our researchers on a regular basis. The information collected on these questionnaires will help us to find out if the new model of care is effective. 'Usual care' will be provided as normal through the NHS and other services. Participants will continue to be followed up in the usual way by their Parkinson's consultant and nurse specialist. They will be given written information signposting them to ways of accessing help for Parkinson's disease via their usual team.
People in Group B will receive the PRIME Parkinson Care model. The PRIME Parkinson team will help support participants to achieve individually set goals for their treatment depending on which symptoms they find most difficult to manage. The PRIME Parkinson team will aim to personalise their care to their particular needs and priorities, and tailor their support accordingly. If they are allocated to receive PRIME Parkinson Care, they will continue to receive their usual care from their Parkinson's team but will also be able to access all aspects of PRIME Parkinson Care. We anticipate that the PRIME Parkinson team will be the main source of support throughout the 2-year period, but they will work closely with the participant's usual Parkinson's specialist. PRIME Parkinson Care has a number of parts:
· A 'case manager' to coordinate the care received from the PRIME Parkinson Care team and other healthcare professionals
· A telephone number to contact the PRIME Parkinson Care team with any queries during office hours
· A Personalised Care Plan booklet which will be completed jointly by the participant and the PRIME Parkinson Care team
· Access to support and education to help them manage their Parkinson's and to achieve their goals
Participants in both groups will be asked to complete some questionnaires at home and to come to hospital for some assessments at the start of the trial, after 1 year and again after 2 years. They will also receive a telephone call from a member of the team approximately every 3 months. The questionnaires will be sent out to participant's addresses for completion at home before attending hospital.

What are the possible benefits and risks of participating?
This trial is designed to improve the way in which care and support is provided for people living with Parkinson's and similar conditions. We have designed a new approach to caring for people with Parkinson's but do not know yet whether this approach is better than our current models of care. Taking part may not benefit every participant directly but it may benefit people with Parkinson's in the future.
We do not expect there to be any additional risks to participants relating to the new type of Parkinson's care itself. Taking part in the trial will involve some assessments with the team and also answering some questionnaires. Some participants may find some of the questionnaire items to be quite personal (e.g. questions about recent thoughts and feelings), and some questions concern intimate topics (e.g. sexual activity, bladder and bowel function). If filling in the questionnaires raises issues or concerns, participants should discuss these with their specialist.

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

When is the study starting and how long is it expected to run for?
January 2021 to June 2025

Who is funding the study?
The PRIME Parkinson RCT has been set up and sponsored by the University of Bristol in collaboration with the Royal United Hospital, Bath. The research is being funded by the Gatsby Charitable Foundation (UK)

Who is the main contact?
Dr Emily Henderson, prime-parkinson@bristol.ac.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
283416

ClinicalTrials.gov (NCT)
NCT05127057

Protocol serial number
IRAS 283416, GAT3676, CPMS 49289

Study information

Scientific Title
PRIME-PD RCT (PRoactive and Integrated Management and Empowerment in Parkinson's Disease): A Randomised Controlled Trial for patients with parkinsonism investigating how PRIME Parkinson augmented model of care versus usual NHS care can achieve goal attainment.

Acronym
PRIME-PD RCT

Study objectives
To determine if the PRIME model of care will augment an individual's ability to achieve their personal goals and positively impact health and disease related metrics and wellbeing in people with parkinsonism.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved on 27/07/2021, London – Harrow Research Ethics Committee (National Health Service Health Research Authority, Level 3, Block B Whitefriars Lewins Mead, Bristol, BS1 2NT, UK; +44 207 104 8246; harrow.rec@hra.nhs.uk), ref no. 21/LO/0387

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
People with Parkinsonism and their informal caregivers are randomised into one of two groups or arms: either PRIME Parkinson multi-component model of care; or usual care.
Participants in the intervention arm of PRIME Parkinson's care will receive an augmented model of care as well as their usual NHS care.
Participants in the placebo comparator arm will receive just their usual NHS care which involves a follow up by consultant or PDNS (approximately 6 monthly), no case management, referral to non-specialist therapists (based on specific criteria) and access to freely available resources such as those provided by Parkinson’s UK (but generally without additional support to identify information and support most suited to an individual’s needs).
Randomisation will be performed via an online system using Sealed Envelope™

Intervention Type
Mixed

Primary outcome(s)
Goal attainment, measured using the Bangor Goal-Setting Interview (BGSI) at 3 monthly intervals over 24 months.

Key secondary outcome(s))
Assessed at baseline (0 months/Visit 1), 12 months (Visit 2) and 24 months (Visit 3):
1. Parkinson's disease assessment measured using MDS-Unified Parkinson's disease Rating Scale (MDS-UPDRS)
2. Non-motor symptom burden measured using MDS-Non-motor rating scale (MDS-NMS)
3. Parkinson's-related quality of life measured using The Parkinson's Disease Questionnaire (PDQ-39)
4. Fear of falling measured using the Iconographical Falls Efficacy Scale (ICON-FES)
5. Global Impression of change measured using the Patients' Global Impression of Change (PGIC)
6. Global Impression of change measured using the Clinical Global Impressions Scale (Improvement)
7. Frailty measured using The Frailty Instrument of the Survey of Health, Ageing and Retirement in Europe (SHARE-FI75+)
8. Frailty measured using Pictorial fit frail scale
9. Frailty measured using clinical frailty scale
10. Sarcopenia measured using the Sluggishness, Assistance in walking, rising from a chair, climb stairs, falls questionnaire (SARC-F)
11. Sarcopenia measured using the Sluggishness, Assistance in walking, rising from a chair, climb stairs, falls, calf circumference questionnaire (SARC-CalF)
12. Malnutrition risk measured using the Malnutrition Universal Screening Tool (MUST)
13. Malnutrition risk measured using the Seniors in the community: risk evaluation for eating and nutrition (SCREEN-II-14)
14. Delirium screened the 4 A's Test (4AT) where applicable
15. Physical performance measured using the Short Physical Performance Battery (SPPB)
16. Physical performance measured using the Timed up and Go (TUG)

17. Physical activity measured using the Incidental and Planned Exercise Questionnaire - WA Version (IPEQ-WA)
18. Endurance measured using 2 Minute Walking Test (2MWT)
19. Endurance measured using 6 Minute Walking Test (6MWT)
20. Gait measured using single and dual task gait assessments
21. Grip strength measured using hand-held dynamometer
22. Falls measured using falls diary
23. Needs assessment measured using Needs Assessment Tool: Parkinson's Disease (NAT-PD)
24. Advance Care Plan data measured using the Edmonton Symptom Assessment System - Revised: Parkinson's disease (ESAS-R-PD)
25. Palliative symptom burden measured using the Palliative Case Outcome Scale - symptom list: Parkinson's disease (POS-S-PD)
26. Hospice utilisation outside place of death captured from hospital and GP records
27. Use of anticipatory medication captured from hospital and GP records
28. Presence of gold standard framework register captured from hospital and GP records
29. Healthcare contacts with hospice and/or palliative care services captured from hospital and GP records
30. Loneliness/social isolation measured using UCLA-Loneliness Scale (3-item)
31. Social participation measured using the English Longitudinal Study of Ageing questionnaire (ELSA)
32. Perceived social support measured using Multidimensional scale of perceived social support (MSPSS)
33. Coping strategy measured using the Brief Coping Orientation to Problems Experienced Inventory (BRIEFCope)
34. Acceptance of illness measured using Acceptance of Illness Scale
35. Capability measured using Measured using the ICEpop Capability measure for older people (ICECAP-O)
36. Patient Activation measured using Patient Activation Measure (PAM)
37. Health-related Quality of Life measured using EuroQol 5D-5L (EQ-5D-5L)
38. Mortality captured from hospital and GP records
39. Healthcare events captured from hospital and GP records
40. Frequency of Parkinson's follow-up captured from hospital and GP records
41. Frequency and type of engagement withPRIMEParkinson care captured from study information
42. Experience of holistic patient-centred care measured using Patient Assessment of Chronic Illness Care (PACIC-26)

Completion date
13/06/2025

Eligibility

Key inclusion criteria
1. Must have a diagnosis of parkinsonism made by a movement disorder specialist
2. Be willing to participate
3. 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
4. Age 18 years and above
5. Resident within the geographical catchment area of RUH Bath

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
214

Key exclusion criteria
1. Patients with drug, infection or toxin induced parkinsonism
2. Patients who lack capacity to participate but do not have anyone who can be a consultee to provide advice regarding the patient's wishes and views
3. Patients with a current medical, cognitive or psychosocial issue or co-enrolment in other study that, in the opinion of the site investigator, would interfere with adherence to study requirements.

Date of first enrolment
02/05/2022

Date of final enrolment
11/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal United Hospital
Combe Park
Bath
England
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 available from the corresponding author on reasonable request to the PRIME programme manager, Julia Carey, 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		07/04/2026	08/04/2026	Yes	No

Protocol article		27/02/2023	04/04/2023	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes