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Live well with Parkinson's

Submission date
04/10/2021

Recruitment status
No longer recruiting

Registration date
26/10/2021

Overall study status
Completed

Last Edited
27/07/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is a progressive brain disorder that affects approximately 127,000 people in the UK. People have increasing difficulty with movement and many other problems including falls, bladder and bowel disturbance, low mood and anxiety, fatigue and sleep disturbance, pain and impaired memory. This can lead to increasing disability, reduced quality of life and unplanned hospital admissions. Management is often complex and management guidelines exist, but access to specialised care is often limited.
Increasingly, patient or carer participation in management (i.e., self-management) is incorporated into health care for long-term conditions (LTCs), as this can allow people to take control and improve outcomes in the face of restricted resources and fragmentation of health care. Currently, no self-management toolkit for people with Parkinson's exists for the public. This study aims to improve the health and well-being of people with Parkinson's by testing the effectiveness of the 'Live Well with Parkinson's' Toolkit compared to usual care in a clinical trial. This study will test if the toolkit works in this and also whether it is cost-effective to be used in the NHS.

Who can participate?
Any person with a diagnosis of Parkinson's disease, that lives at home can participate.

What does the study involve?
The toolkit is available online and in paper and aims to help increase the active involvement of people with Parkinson's in the management of their care, including how to keep healthy and independent, where to access resources and how to manage their Parkinson's. The toolkit is facilitated by a 'Supporter' who will offer up to six one-to-one sessions with the participants in which they will be directed to relevant information and advice on symptoms that may be bothering them as well as identifying what living well means to them and what steps they can take to achieve this.

What are the possible benefits and risks of participating?
It is hoped that the Live Well with Parkinson's toolkit will reduce disability and hospital admissions and improve day-to-day living and quality of life. No specific risks have been identified.

Where is the study run from?
The study team is based at the Royal Free London NHS Trust and UCL (UK)

When is the study starting and how long is it expected to run for?
July 2021 to August 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
rf.livewellparkinsons@nhs.net

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
294372

Central Portfolio Management System (CPMS)
50058

Study information

Scientific Title
Live Well with Parkinson’s (part of the program: personalised care for people with Parkinson’s Disease: PD-Care WP4)

Acronym
PD-Care WP4

Study objectives

The study's main objective is to evaluate whether the “Live Well with Parkinson’s” facilitated self-management toolkit enables personalised care, reduces disability and preventable hospital admissions, and improves quality of life for community-living people with Parkinson’s.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/10/2021, London – Harrow REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44(0)207 104 8356; harrow.rec@hra.nhs.uk), ref: 21/LO/0562

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

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

Interventions
The intervention consists of access to the ‘Live well with Parkinson’s’ toolkit (either online or paper format) and supporter sessions.
The toolkit was co-designed with people with Parkinson’s, carers, health and social care professionals and Parkinson’s disease experts. It is based on evidence from effective health promotion interventions and incorporates theory-based behaviour change techniques. The research team conducted two systematic reviews synthesising evidence on self-management techniques for people with Parkinson’s and explored the barriers and facilitators of using them. These reviews were supplemented with interviews with people with Parkinson’s, carers, and health care professionals to explore the challenges people with Parkinson’s and those that support them face. Combining this evidence with a series of co-design workshops and user testing led to the development of the toolkit of potential strategies, drawing on theory and evidence-based techniques, to help overcome the challenges people with Parkinson’s face and to support them to live independently.
The key theories the toolkit draws upon are:
1) Person-centred care: working in partnership with the participant to develop a plan to address their needs or priorities.
2) Self-management: teaching participants to actively identify challenges and solve problems associated with their illness themselves with support.
3) Behaviour change model: This suggests that all behaviours depend on the presence of three core determinants: capability, opportunity, and motivation. Therefore, any changes the participant would like to make to their behaviour must incorporate those three components.
4) Asset based approached: By encouraging participants to focus on their assets (i.e., what they enjoy and can do) as opposed to their deficits (i.e., what they can’t do) may encourage some to maintain the positive behaviours.

The toolkit consists of 64 information sections on what Parkinson's is, symptoms, therapies /treatments, optimising wellbeing, and practical advice which were identified as important in co-design with people affected by Parkinson's and experts in the area. Each content section has been through review by two members of the team, an expert in the specific area and by PPI team members, and subject to 'readability' review.
The toolkit also comprises personalised sections on the following:
• About Me – including information on their contracts, support and planning future care.
• My Health – including information on their health conditions, medication, treatments, and research involvement.
• Symptom Review – a list of symptoms they experience and the severity of them. This will allow the participants to identify and explore the symptoms they are experiencing.
• My Wellbeing – to identify health behaviours they would like to maintain or improve.
• My Tracker – to track medications, activities, and symptoms. This section allows participants to identify patterns and specialists to get a better idea of what participants are experiencing.
• Appointments/calendar - In our co-design process, participants asked for a calendar within the toolkit, so that all their healthcare appointments could be stored in one place.
• To do lists/Notes – a way to note or list anything that participants feel is useful.

Both the paper and online version can be shared with participants' carers and HCPs if they wish. Participants can share the whole toolkit or select sections.
Intervention supporter sessions.

Participants, and, if the participants would like, the carer, will receive around four (up to six if needed) sessions over six months led by a 'supporter'. The supporter will be a trained professional with a background in healthcare (e.g.psychology, occupational therapy, nursing), social care or third sector (e.g. care navigation, social prescribing) with some experience of working/caring for people with Parkinson's and will receive training to deliver the intervention. The sessions will be around 60-90 minutes for the first two sessions and around 30 minutes for the remaining sessions. The aim of the sessions is to encourage the participants to self-manage their condition by using the 'Live well with Parkinson's' toolkit. The supporter will follow a manual and checklists covering support navigating the toolkit,
understanding the benefits of using the different sections and assist in the creation of wellbeing priorities (goals) and use behaviour change techniques to help implement priorities long-term. These sessions will be conducted online via Zoom, by telephone or face-to-face when appropriate.

Randomization:
Participants will be randomised by PRIMENT CTU (using web-based service, 'Sealed Envelope') in a 1:1 ratio to the intervention or treatment as usual (TAU) group:
(1) Intervention: TAU (see below) plus access to 'Live well with Parkinson's' toolkit, supported by trained service providers
or
(2) TAU: usual care from existing sources (GP, Parkinson's specialist service +/- NHS PDNS).
Treatment as usual in the current NHS, is delivered by primary care together with secondary care (neurology and geriatrics) consultations every six to 12 months, with a PDNS who provides information, reviews and a telephone service for queries between appointments. Referrals to other specialities, therapists (physiotherapy, occupational therapy, speech and language therapy, social care services etc) are made as appropriate.

Participants will be assessed remotely or face-to-face at baseline and 6 and 12 months. Assessors will be blind to treatment group.

Outcome measurements have been chosen to capture important domains that might change with the intervention, including potential mechanisms (e.g., self-efficacy), using the best valid and reliable measures available, with shorter instruments chosen where possible to reduce participant burden. The outcome assessments will take approximately 90 minutes to complete, which based on previous studies in similar populations is an acceptable length.

Ancillary Studies
Participants will be given the opportunity to donate a saliva sample for genetic analysis for use in future research unrelated to the aims of the current study. In addition, in order to assess changes in motor function better, electronic measurements, which have been proposed as more accurate than clinical judgment on rating scales, are included as
optional assessments: A wearable movement sensor, which is being used in the UK Biobank study (Axivity; https://axivity.com/) and other clinical trials in the UK (https://axivity.com/case-studies/interval), to be worn at the trunk (e.g. on the belt) will be provided and worn for 7 days after assessment.

Internal pilot
The first six months of recruitment (n=80) will form an internal pilot with stop/go criteria, to test trial recruitment procedures and participant willingness to be randomised. The stop/go progression criteria at 6 months are the following:
1. Minimum recruitment and randomisation rate of 70% of the target of 80 people within 6 months (10 people per month for first 2 months during set-up phase, followed by 20 per month for 4 months).
2. Minimum uptake of the intervention of 70% of participants (evidence of use of the toolkit /attendance at follow-up appointments).
3. Minimum retention rate of 70% at 6 months (completion of main outcome measures).
4. No serious intervention-related adverse events.
If the trial is successful in meeting these criteria the full RCT will proceed, and data from the pilot phase contribute to the outcomes. Recruitment rate and attrition will be monitored very closely and if levels are less than expected contingency measures will be put in place (e.g. expand to further study sites, introduce incentives).

Intervention Type
Other

Primary outcome(s)
Quality of life measured using the Parkinson's Disease Questionnaire (PDQ-39) at baseline, 6 and 12 months

Key secondary outcome(s)
All measured at baseline, 6 and 12 months:
From people with Parkinson’s:
1. Non-motor Parkinson’s symptoms measured using Movement Disorders Society - Unified Parkinson’s Disease Rating Scale (MDS-UPDRS) Part I and II (Mentation, Behaviour, Mood and ADL).
2. Motor Parkinson’s symptoms measured using MDS-UPDRS part 3 (motor), part 4 (motor-complications including Off-time) and total score
3. Non-motor Parkinson’s symptoms measured using Non-Motor Symptoms Scale (NMSS, 30 items)
4. Quality of life measured using EQ-5D-5L: Quality of life (5 items and visual analogue scale)
5. GHQ12: Psychological well-being (12 items)

6. Valuation of Informal Care measured using Client Service Receipt Inventory-shortened, adapted for Parkinson's from iMTA Valuation of Informal Care Questionnaire (iVICQ), Health /social care resources, out of pocket costs, financial impact on carers, welfare payments and living arrangements
7. Self-Efficacy for Managing Chronic Disease (6- Item Scale)
8. ICECAP-O: capability (5 items)
9. Patient activation measured using Patient Activation Measure (PAM)
10. Medication, deaths measured using patient records
11. Cognition measured using MoCA at baseline only.

Health economic evaluation will include incremental cost per quality-adjusted and capability-adjusted life year gained from i) health/social care perspective and ii) societal perspective and a decision-analytic model extrapolating costs/consequence beyond the trial.

From carers:
11. Carer burden measured using Zarit carer burden inventory (22 items)
12. Carer quality of life measured using Carer Quality of Life questionnaire for Parkinsonism (26 items)

Completion date
31/08/2024

Eligibility

Key inclusion criteria
Community-dwelling adults with a confirmed diagnosis of Parkinson's Disease, (defined using UK Brain Bank Criteria), including those with dementia diagnosed at least 1 year after Parkinson's diagnosis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
346

Key exclusion criteria
1. Atypical Parkinsonism
2. Currently an inpatient or living in a care home
3. Life expectancy <6 months

Date of first enrolment

01/11/2021

Date of final enrolment
06/06/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
Royal Free Hospital
Pond Street
London
England
NW3 2QG

Study participating centre
Luton & Dunstable University Hospital
Bedfordshire Hospitals NHS Foundation Trust
Lewsey Rd
Luton
England
LU4 0DZ

Study participating centre
University Hospital Lewisham
Lewisham High Street
London
England
SE13 6LH

Study participating centre
Lister Hospital
Coreys Mill Lane
Hertfordshire
Stevenage
England
SG1 4AB

Study participating centre

King’s College Hospital
Denmark Hill
London
England
SE5 9RS

Study participating centre
Southend University Hospital
Southend University Hospital NHS Foundation Trust
Prittlewell Chase
Westcliff-on-sea
England
SS0 0RY

Study participating centre
Homerton University Hospital
Homerton Row
London
England
E9 6SR

Study participating centre
University College London Hospital
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
England
NW1 2PG

Sponsor information

Organisation
Royal Free London NHS Foundation Trust

ROR
https://ror.org/04rtdp853

Funder(s)

Funder type

Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-1016-20001

Funder Name
National Institute for Health 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
The datasets generated during and/or analysed during the current study are/will be available upon request from PRIMENT CTU Data Management Group on priment@ucl.ac.uk and will only be possible in collaboration with members of the PD-Care Trial Management Group, pd-care@ucl.ac.uk.
The data underlying this study contains sensitive information and cannot be made publicly available, according to PRIMENT CTU Data Management Group. PRIMENT CTU is a UK Clinical Research Collaboration (UKCRC) registered clinical trials unit and is based at UCL (see here for more information: https://www.ucl.ac.uk/priment).
The study collects quantitative data from patient assessments as well as interview data, which will become available after data processing and cleaning, a week as initial analysis at the end of the study. It will be made available to bona fide researchers upon reasonable request, observing data protection rules.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Clinical and cost-effectiveness secondary outcomes	21/07/2026 05/12	27/07/2026 07/12	Yes	No

Protocol article		/2023	/2023	Yes	No
HRA research summary			28/06 /2023	No	No
Other publications	Single-group, pre–post feasibility study to evaluate the feasibility and acceptability of this toolkit, ahead of the RCT	21/08 /2025	04/09 /2025	Yes	No
Participant information sheet	version 1.1	01/09 /2021	21/10 /2021	No	Yes
Protocol file	version 1.4	23/03 /2023	28/11 /2024	No	No
Statistical Analysis Plan	Main trial version 1.3		26/11 /2024	No	No
Statistical Analysis Plan	Process evaluation version 1.2	26/11 /2024	04/06 /2025	No	No
Statistical Analysis Plan	Underserved groups version 0.2	26/11 /2024	04/06 /2025	No	No
Study website	Study website	11/11 /2025	11/11 /2025	No	Yes