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iSupport-PD: a digital intervention for care partners of people with Parkinson’s and cognitive impairment

Submission date 04/06/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 07/06/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 10/03/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English Summary

Background and study aims
In the UK, the number of people with Parkinson's disease (PD) will reach over 168,000 by 2025. At diagnosis, 19% of people with Parkinson's will have cognitive impairment, with symptoms including memory loss, difficulty concentrating and anxiety. Up to 78% of people with Parkinson's will develop Parkinson's dementia with symptoms such as confusion, hallucinations, and depression. As symptoms of Parkinson’s progress, people with PD require increasing support from an informal (unpaid) care partners to help maintain quality of life. 69% of carers of people with moderate to advanced PD report moderate to severe levels of strain. Lack of adequate support leads to carer breakdown and avoidable NHS and social care costs. Despite their important role, there is a scarcity of support for carers of people with PD with cognitive impairment. Making sure carers maintain their physical and mental health is crucial. The World Health Organization has developed iSupport, a programme for carers of people with dementia that aims to prevent and/or decrease the mental and physical health problems associated with caring and improve quality of life. It is available online, or as a paper booklet, and provides information and training for carers to take care of themselves, provide everyday care and deal with complex behaviour changes. iSupport is a useful resource, but it does not currently meet the specific needs of carers of people with Parkinson's with cognitive impairment.
The aims of this study are to: (1) adapt iSupport for carers of people with Parkinson's with cognitive impairment; (2) check the programme is relevant and useful for these carers; and (3) test that the research procedures for a future evaluation are practical and achievable.

Who can participate?
Adults (aged 18+ years) who self-identify as an unpaid carer (partners, children, friends etc) of a person with Parkinson’s and cognitive impairment, who is not living in a full-time care facility, caring at least weekly for at least 6 months. The care recipient must have symptoms of cognitive impairment (through self-report of the care partner, to reflect the ‘real world’ application of iSupport-PD).

What does the study involve?
Participants are randomly allocated to either use the iSupport-PD website or usual care.

Different modules within the iSupport-PD website provide information, skills training, and support using problem-solving, communications skills, stress management (e.g. relaxation), and cognitive behavioural therapy (e.g. psychoeducation, cognitive reframing, behavioural activation) techniques that care partners can work through independently.

What are the possible benefits and risks of participating?
There is the potential for participants to experience emotional distress caused by data collection. It is necessary to collect this data, but the researchers will signpost participants to support groups, Parkinson's UK services and GP services. Some participants may find the time to complete questionnaires burdensome, however, the study will only use validated questionnaires agreed upon by the PPI group.
It is intended that iSupport PD will enable carers to have the knowledge, skills, and confidence to better manage their own health and well-being; to better support and co-manage the symptoms of the person with PD with cognitive impairment; to feel empowered in their role and become a valuable member of the multidisciplinary team; and to successfully access available support and resources. This could improve quality of life for both carers and people with PD and lead to better utilisation of health and social care resources, reduce hospital admissions and long-term care home placement. Ultimately, iSupport-PD could support the carers of over 10 million people with PD around the world. The distribution of iSupport-PD and the research findings have the potential to raise health and social care professional awareness of carer needs, along with the need to signpost to appropriate information and support and recognise the value of the carer as an integral member of the multidisciplinary team and feel better able to support carers.

Where is the study run from?
Northumbria University (UK)

When is the study starting and how long is it expected to run for?
June 2023 to November 2025

Who is funding the study?
National Institute for Health and Care Research - Research for Social Care NIHR204259 (Research for Social Care Competition 4) (UK)

Who is the main contact?
1. Prof. Annette Hand, a.hand@northumbria.ac.uk
2. Mrs Dilupa Samarakoon, dilupa.samarakoon@northumbria.ac.uk

Study website
https://hosting.northumbria.ac.uk/isupportpd/

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
325361

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 62249, IRAS 325361

Study information

Scientific Title
Development and feasibility trial of iSupport-PD, a digital intervention for carers of people with Parkinson’s and cognitive impairment

Acronym
iSupport-PD

Study hypothesis
This study will assess if it is feasible, useful and acceptable to adapt iSupport for care partners of people with Parkinson's and cognitive impairment and to conduct a larger definitive trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/03/2024, Northumbria University Ethics Committee (Northumbria University Sutherland Building, College Street, Newcastle upon Tyne, NE1 8ST, UK; +44 (0)191 232 6002; ethicssupport@northumbria.ac.uk), ref: IRAS 325361

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Condition

Carers of people with Parkinson's and cognitive impairment

Interventions

WS1: Adaption of iSupport
The adaptation of iSupport will follow the validated person-based approach (PBA) to intervention development. The adaptation process will be guided by a stakeholder panel consisting of researchers, PPI, health and care professionals, and Parkinson's UK representatives. Combined think-aloud and semi-structured interviews will be conducted with carers, who will be asked to share aloud their immediate and detailed reactions to the intervention content, their experiences of caring for a person with PD cognitive impairment, and their views on how the acceptability and accessibility of iSupport might be improved. PBA guiding principles, summarising the intervention design objectives and key intervention features that will maximise intervention engagement among this population, will be created from the outset and refined throughout the adaptation. The intervention refinement process will be iterative, moving between data collection and analysis, programme theory development, and intervention modification.

WS2: Feasibility RCT
A feasibility randomised controlled trial will be conducted comparing the provision of iSupport-PD to usual care. Randomisation will be performed on a 1:1 basis by computer using dynamic allocation. The feasibility of a future RCT will be investigated using progression criteria designed according to the Consolidated Standards of Reporting Trials (CONSORT) extension for reporting feasibility trials. Progression criteria will be assessed on a traffic light system of green/amber /red zones. Recruitment of participants based on a target of n = 100 (green >75 amber 50 - 74, red <=50). Intervention engagement: assessed by number of intervention participants who have used iSupport-PD (green >=70%, amber 50-69%, red 50%). Recruited participants completing each follow-up (green >=75%, amber 50-69% red <50%). Ability to collect outcome data (assessed on baseline and follow-up) where each outcome measure would be a candidate for removal in a larger RCT if less than 85% of participants attempt to complete a measure (green >=85%, amber 70-84%, red <70%).

WS3: Health Economics
A prospective economic evaluation will be rehearsed to develop and refine methods for a subsequent definitive trial. The focus will be on accurately identifying, quantifying, and valuing the additional costs of delivering the intervention and the potential resource implications versus usual care. The costing approach will incorporate an NHS and personal social care perspective. All costs will be combined to rehearse the methods for total cost estimation in a subsequent definitive trial. The feasibility of conducting a cost-utility analysis will be explored using Quality-Adjusted Life Years (QALYs) derived from the EQ-5D-5L collected at baseline, 3, 6 and 12 months post-randomisation. In addition, the ASCOT carers questionnaire will be used to investigate the feasibility of conducting a cost-utility analysis using social QALY. Issues relevant to sensitivity analysis will be explored to help understand how best to deal with statistical imprecision and other uncertainties in the full trial.; WS4: Process Evaluation, Alongside the feasibility study, a process evaluation will be conducted in line with MRC guidance for process evaluation of complex interventions. Up to 20 trial participants will be selected to take part in semi-structured interviews to explore their views and experiences of using iSupport-PD. Purposive sampling will

be used to recruit carers from a range of backgrounds. Participants will be asked about their views and experiences of engaging with the intervention and its recommended activities, being in the trial, and caring for a person with PD with cognitive impairment and how the intervention may have changed their abilities to care and cope with this role. Objective usage data (e.g. frequency and length of use, modules/lessons/pages visited) will be collected automatically by the website to measure intervention engagement. Participants allocated to the intervention group will also be asked at 6 and 12 months to complete a self-report questionnaire assessing adherence to the behavioural techniques/activities recommended by the intervention (e.g. relaxation). We will also assess intervention reach, including the percentage of participants allocated to the intervention arm who accessed the intervention and a description of the sample characteristics of those who did or did not access the intervention.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The feasibility of conducting a larger powered randomized controlled trial to evaluate the effectiveness and cost-effectiveness of iSupport-PD versus usual care. Feasibility will be determined through a composite of successful recruitment, data collection completeness, intervention engagement, study attrition rate, suitability and sensitivity of outcome measures, and feasibility of collecting data on costs and health and social care use. Participant engagement with iSupport-PD will be investigated using data collected from Matomo Analytics and will include data such as number of accesses and length of time spent on each page. Data will be collected at baseline, 3 months after baseline, 6 months after baseline, and 12 months after baseline.

Secondary outcome measures
Measured at baseline, 3 months after baseline, 6 months after baseline, and 12 months after baseline:
1. Caregiver burden measured using the short form 12-item Zarit Burden Interview (ZBI-12)
2. Depression measured using the Center for Epidemiologic Studies Short Depression Scale (CES-D-10)
3. Anxiety measured using the generalised anxiety disorder scale (GAD-7)
4. Resilience measured using the Resilience Scale (RS-14)
5. Quality of relationship measured using the Dyadic Relationship scale
6. Quality of life of carers measured using the Parkinson's Disease Questionnaire for Carers (PDQ-C)
7. Self-efficacy measured using the General Self-Efficacy scale
8. Positive aspects of caregiving measured using the Positive Aspects of Caregiving Scale (PACS)
9. Health-related quality of life measured using the EuroQol-5 Dimension (EQ-5D-5L)
10. Social care related quality of life measured using the ASCOT-Carer SCT4
11. Health and social care service use and associated costs: an economic evaluation will be conducted by costing of resources (capital equipment, staff time, length of stay in hospital and changes in social care) and carrying out a cost-utility analysis by exploring Quality-Adjusted Life Years (QALYS) derived from the EQ-5D-5L data collected at baseline, 3,6 and 12 months post-randomisation

Overall study start date

01/06/2023

Overall study end date
30/11/2025

Eligibility

Participant inclusion criteria
1. Adults (aged 18+ years) who self-identify as an unpaid carer (partners, children, friends, etc) of a person with Parkinson's and cognitive impairment, who is not living in a full-time care facility, caring at least weekly for at least 6 months
2. The care recipient must have symptoms of cognitive impairment (through self-report of the care partner, using the DIAMOND toolkit, to reflect the 'real world' application of iSupport-PD)

Participant type(s)
Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Participant exclusion criteria
1. Receiving psychological treatment from a mental health specialist at the time of recruitment
2. Unable to comprehend written English
3. No access to the internet
4. Unable to give informed consent to the trial
5. The care recipient has a diagnosis of an atypical Parkinsonian syndrome (i.e. progressive supranuclearpalsy, multiple system atrophy, corticobasal degeneration or Lewy body dementia)

Recruitment start date
08/07/2024

Recruitment end date
30/06/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Northumbria at Newcastle
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Sponsor type
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ROR
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Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR204259

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/11/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

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