Development and Feasibility Trial of iSupport-PD, a Digital Intervention for carers of people with Parkinson's and cognitive impairment

iSupport-PD

Study Protocol

Version 2.1

FULL/LONG TITLE OF THE STUDY

Development and Feasibility Trial of iSupport-PD, a Digital Intervention for carers of people with Parkinson's and cognitive impairment

SHORT STUDY TITLE / ACRONYM

iSupport-PD

PROTOCOL VERSION NUMBER AND DATE:

Version 2.1

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RESEARCH REFERENCE NUMBERS

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KEY STUDY CONTACTS

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Study Co-ordinator	Dr Helen Cartner
Sponsor	Northumbria University
Joint-sponsor(s)/co-sponsor(s)	University of Southampton
Funder(s)	National institute of Health Research (NIHR) Research for patient benefit (RFPB) Research for Social Care funding stream (RfSC)

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STUDY SUMMARY

Study Title	Development and Feasibility Trial of iSupport-PD, a Digital Intervention for carers of people with Parkinson's and cognitive impairment
Internal ref. no. (or short title)	iSupport-PD
Study Design	Feasibility RCT, mixed methods design
Study Participants	Care partners of people with Parkinson's and cognitive impairment
Planned Size of Sample (if applicable)	100
Follow up duration (if applicable)	12 months
Planned Study Period	12 months
Research Question/Aim(s)	To explore the feasibility of a randomised controlled trial (RCT) for iSupport-PD and the acceptability of the intervention

ROLE OF STUDY SPONSOR AND FUNDER

Northumbria University assume overall responsibility for the ethical governance of the study.

ROLES AND RESPONSIBILITIES

Trial Management Group

The study management committee, comprising of leads and co-applications will meet on a monthly basis.

Patient and Public Involvement Group

We will also consult with our lay advisory group to gain their feedback on intervention content, suggested modifications, recruitment materials, and interview topic guides. This group, led by the PPI lead will meet on a quarterly basis.

Stakeholder involvement

The adaptation process will be guided by a stakeholder panel consisting of researchers, PPI, health and care professionals, and Parkinson's UK representatives. The panel will meet approximately 6 times throughout the intervention development stage to interpret qualitative findings and oversee and input into all design decisions.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigators:

Signature:
.....

Date:
...../...../.....

Name: (please print):

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STUDY PROTOCOL

This protocol sets out the Feasibility Trial of iSupport-PD, a Digital Intervention for carers of people with Parkinson's and cognitive impairment. The adaptation and development of iSupport has already been completed, this protocol is in relation to the feasibility randomised controlled trial.

1. Background and Rationale

1.1 What is the problem being addressed?

Parkinsons Disease (PD) is the second most common neurodegenerative condition in the UK, affecting an estimated 145,519 people (1). The prevalence of PD in the UK is expected to rise by 18% between 2018 and 2025 to over 168,000 (1). PD is not just a condition of older age, young onset PD (21-40 years) accounts for 10% of the PD population (2). PD is a complex condition that results in motor and non-motor symptoms (sleep problems, constipation, depression and behavioural changes) (3). Cognitive impairment (both with and without dementia) is a well-recognised complication of PD with significant clinical impact (4). At diagnosis, 19% of people with PD have some level of cognitive impairment (5). Up to 78% of people with PD will develop Parkinson's disease dementia (6). As symptoms progress, people with PD require increasing support from carers (paid or unpaid) to help maintain quality of life (7). Most care needs are met by informal (unpaid) carers; this role is often associated with increased carer stress and strain, reduced quality of life, and impaired physical and mental well-being, particularly when the person with PD has cognitive impairment (8).

Our research team recently explored levels of carer strain in PD and identified that 69% of carers reported moderate to severe levels of strain, as identified via the Carer Burden Inventory (CBI) (9). A recent listening exercise, led by Parkinson's UK with 40 PD carers, highlighted accumulating stress and strain due to caring responsibilities. Such strain can lead carers to neglect their own needs, which commonly leads to deteriorating mental or physical health, with resulting impacts on their ability to care for the person with PD. In the UK, carer breakdown leads to unplanned hospital admissions and care home placement (10).

1.2 Why is this research important?

Sustaining the health and capabilities of these carers is a public health priority. The Government's mandate to NHS England for 2018-19 included an expectation that care should routinely be identified and given access to information and advice about the support available (11). NICE guidance [NG150] (12) recommends carers are offered training and psychoeducation to help them develop care skills and manage their own physical and mental health. Despite their important role, there is a lack of support for carers of people with PD.

Early intervention and consideration of carer needs is required to prevent carers experiencing crisis, and poor physical and psychosocial health (9, 13). However, carer interventions often come too late, with stress treated as an inevitable caring side effect. Access to appropriate, cost-effective support for carers has the potential for significant impact on health outcomes and health and social care resource use. Self-help interventions that individuals can complete, at a convenient time and place, would be particularly useful for carers who often find attending face-to-face or time-intensive interventions more difficult. There is a need to extend the limited and variable support currently available to carers through health and social care services and the support commonly accessed via charities, such as Parkinson's UK who are supporting this project.

We carried out a PPI focus group with 6 PD carers, which highlighted how limited carer support exacerbated already high levels of strain and how carers lacked confidence, or knowledge, to ask for support and struggled with the resilience and motivation needed to cope with caring. They described the project as "imperative" and the proposed intervention a "game changer" and a much-needed source of support that could help save health and social care resources. There is growing recognition of informal carers at policy level, but programmes that

support carers' training, counselling or access to self-help groups are often insufficient or difficult to access, leaving people unsupported to manage the emotional and financial burden of being an informal carer (14).

1.3 Brief review of published evidence

A scoping review by team members identified 17 studies evaluating psychosocial interventions for PD carers. There was mixed evidence regarding the effectiveness of the interventions, however, the overall trend was an improvement in quality of life and reduction in carer burden, anxiety, and depression. Only 7 studies evaluated psychosocial interventions targeting carers only, with most studies targeting both people with PD and carers. None of the interventions examined self-help or digital interventions, with most interventions being delivered in a group or 1:1 by a health professional. Therefore, we have little understanding of how acceptable, feasible and effective self-help interventions are for carers of people with PD with cognitive impairment. Research is needed to understand carer support needs and how to prevent deterioration of their health (9, 13).

2. RESEARCH AIMS

The research aim is to determine the feasibility of conducting a powered RCT to investigate the effectiveness and cost effectiveness of the iSupport-PD toolkit to support to support carers of those with PD compared to usual care.

2.1. Objectives

The objectives of the trial are:

- To assess the feasibility of a parallel cost-effectiveness analysis
- To conduct a process evaluation to explore intervention and trial acceptability

3. Feasibility RCT

The iSupport-PD study is a two-arm, feasibility randomised controlled trial composed of two arms which will recruit participants in the UK (England, Scotland, Wales and Northern Ireland) and will assess the feasibility, acceptability, and uptake of conducting a larger trial. This Protocol has been developed using the SPIRIT checklist (23).

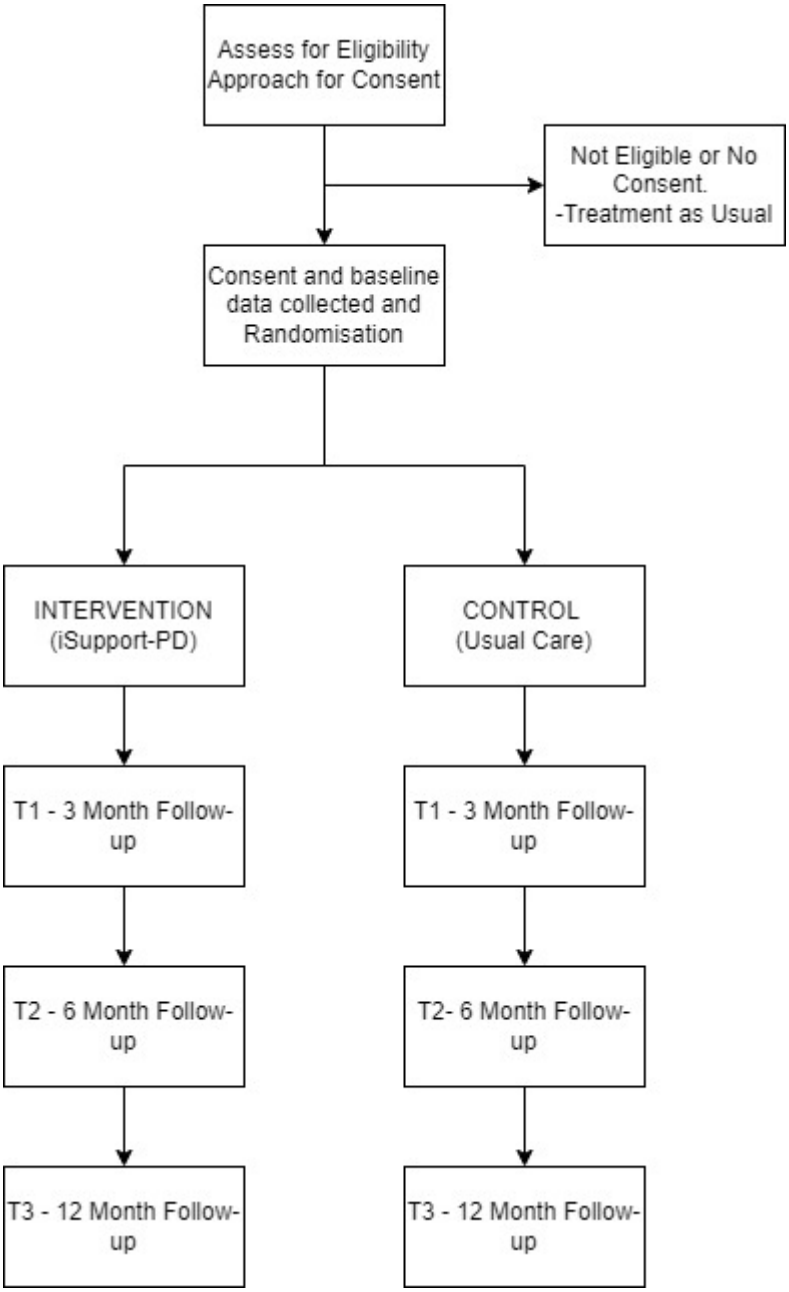

Figure 2: Flow of participants through study

3.1 Recruitment

Parkinson's carers (age 18+) in Wales, Scotland, Northern Ireland and England will be recruited through a range of approaches. Patient and Public Involvement (PPI) groups and Parkinson's UK will promote the research through research interest groups, Parkinson's support groups, and social media to promote self-referral. The Parkinson's UK research database, an online self-registration service, that enables people with Parkinson's and carers to register their interest in taking part in research, will be utilised to identify potential participants. Our study partners Parkinson's UK and Carers Trust, and other non-statutory organisations (e.g., Centre for Ethnic Health Research, LGBT foundation) will promote the study through their networks and to regional groups, in order to reach a diverse range of carers. Participants may be recruited through posters within their local Specialist clinic, or by being approached by a clinician who is directly involved in the care of the person with Parkinson's whom they care for.

3.2. Inclusion Criteria

Participants will be:

- Adults aged 18 or over
- Self-identify as an unpaid carer (e.g. partners, children, friends) of a person with Parkinson's and cognitive impairment,
- Provide caring activities at least weekly for at least 6 months.
- The care recipient has to have symptoms of cognitive impairment (through self-report of the care partner, using the DIAMOND toolkit (24), to reflect the 'real world' application of iSupport-PD).
- Provide care for someone not living in a full-time care facility.

3.3 Exclusion Criteria

Exclusion criteria consists of:

- Participants receiving psychological treatment from a mental health specialist at the time of recruitment.
- Participants being unable to comprehend written English, having no access to the internet, being unable to give informed consent to the trial
- If the care recipient has a diagnosis of an atypical Parkinsonian syndrome (i.e. Progressive Supranuclear palsy, Multiple system atrophy, Corticobasal degeneration or Lewy Body Dementia).

3.4 Trial Consent Procedure

Informed Consent will be obtained from potential participants before they are enrolled into the feasibility trial. Potential participants will sign an electronic consent form after receiving trial information and consent forms via email. Before signed consent can be given, participants will have a one-to-one phone with a researcher. The researcher will use a telephone checklist to ensure all questions about the study have been answered. At this point, in line with the MCA, the researcher would only formally assess capacity if concerns regarding capacity were suspected. Should any potential participant be deemed as lacking capacity they would be excluded from the study.

3.5 Randomisation procedure

Randomisation will be performed on a 1:1 basis by computer using dynamic allocation, in particular minimisation, to ensure groups are balanced for carer age, relationship to person with PD, gender, and baseline quality of life score. Use of dynamic allocation will also protect against subversion(25).
Randomisation will occur after participants complete the study validated questionnaires that include caregiver burden, caregiver mental wellbeing, caregiver quality of life, quality of caregiver relationship, and health and social care service usage. The outcome measures used are: 12-item Zarit scale, CES-D10, GAD-7, RS-14, Dyadic Relationship scale, PDQ-C, General Self-efficacy scale, positive aspects of caregiving scale, EuroQol EQ-5D-5L, Adult Social Care Outcomes Toolkit (ASCOT) for carers. In addition, they will be asked to complete a questionnaire that will collect health and social care resource use data. This data will provide a baseline assessment for each participant.
Allocation will be hidden using the sealed envelope method whereby the information needed for randomisation, collected at baseline, will be placed in an opaque sealed envelope by a researcher and given to a separate researcher to conduct the randomisation independently.

3.6 Unblinding procedure

It is not possible to blind individual participants to the feasibility study. However, researchers will remain blinded during data collection. The exception to this will be the co-investigator who is conducting the process evaluation.

3.7 Withdrawal of participants

Participants are free to withdraw at any point during the trial without any impact on their future health and care. Unless specifically withdrawn, participant data will be used up until the point of withdrawal.

4. Trial procedures

4.1 Planned intervention

The intervention group will be those who are offered provision of the iSupport-PD digital intervention, which provides carers of those with Parkinson's with information, skills training, and support using problem-solving, communications skills, stress management (e.g. relaxation), and cognitive behavioural therapy techniques. ISupport-PD is an additional intervention for participants alongside any concomitant care they may receive. Furthermore, there are no known issues with concomitant treatments and no treatments will be excluded.

ISupport-PD is a digital intervention, adapted from iSupport, which was developed by the World Health Organization (WHO), that is freely available for carers of people with dementia (26). ISupport-PD aims to prevent and/or decrease the mental and physical health problems associated with caring and improve quality of life. It provides 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. A 'generic' version of iSupport is available, but WHO recommends that this is adapted to meet the cultural, language, and contextual needs of each carer group, with guidelines available to support this process. There are several advantages of iSupport. It was developed in collaboration with experts and dementia carers following evidence-based guidelines. Initial user tests have shown it to be usable (16), many of its techniques have been shown to be effective and acceptable (16, 26), but it is not currently suitable for carers of people with PD with cognitive impairment in its current form. The age range of people with PD and their carers is wider than dementia and PD management is more complex. In addition to dementia, carers also need to manage a range of fluctuating, motor and non-motor symptoms, and complex medication regimes, whilst navigating multiple health and social care services.

4.2 Comparison group

The comparison group will not be given access to iSupport and will not be given any additional interventions beyond their 'usual care'. Following final data collection the participants will allocated to the comparison group will be offered access to iSupport for up to 6 months.

4.3 Setting and context

This feasibility study will be undertaken with care partners of those with Parkinson's with cognitive impairment who live in the UK (England, Scotland, Wales, Northern Ireland). Carers who meet the inclusion criteria and consent to take part in this study and are randomised to the intervention arm will be offered access to iSupport-PD. The research site for this feasibility study will be Northumbria University with members of Southampton University as collaborators. The iSupport-PD intervention and data will be hosted at Northumbria university. All researchers will follow the same working procedures as described in this protocol.

4.4 Sampling and sample size

For a feasibility study, no formal sample size calculation is required. The aim for this study is to recruit 100 eligible participants (50 in each arm). From this we will be able to estimate a participation rate of 50% to within a 95% confidence interval of +/- 10% where the confidence interval is estimated as 1.96 x (p x (1-p)/n) (27). Furthermore, this sample size should be sufficient to estimate the standard deviation an effect size of the main outcome measures to enable a sample size calculation for the full-scale trial.

4.5 Selection of participants

The expression of interest form will collect optional participant demographic information. This information will be used to ensure that a diverse range of participants are invited to take part in this feasibility study. Researchers will monitor this optional demographic data in order to adjust recruitment strategies where needed to target underrepresented populations. This will inform recruitment strategies for a future definitive trial.

Participants who meet inclusion criteria and are invited to take part in the feasibility study, will provide consent and complete baseline assessments. Following this they will be randomised to the intervention or control group and the outcome communicated to them in an email, internet bases service, or telephone. Those randomised to the intervention group will receive access to the iSupport-PD intervention. The control group will be given access to iSupport-PD after study completion.

4.6 Outcome measures

The primary outcome is to determine the feasibility of conducting a larger powered Randomised 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 Google Analytics and will include data such as number of accesses and length of time spent on each page.

In order to plan for a full intervention evaluation study we will also collect secondary outcome measures, to see if it is feasible, and appropriate to collect these data. We will collect data on caregiver burden, caregiver mental wellbeing, caregiver quality of life, quality of caregiver relationship, and health and social care service usage. The outcome measures which will be used are: 12-item Zarit scale, CES-D10, GAD-7, RS-14, Dyadic Relationship scale, PDQ-C, General Self-efficacy scale, positive aspects of caregiving scale, EuroQol EQ-5D-5L, Adult Social Care Outcomes Toolkit (ASCOT) for carers. In addition, a questionnaire will be designed to collect health and social care resource use data.

Caregiver burden will be measured using the short form 12-item Zarit Burden interview (ZBI-12) (28). Item responses range from 0 (never) to 4 (almost always), and higher scores indicate greater distress. Depression will be measured using the Center for Epidemiologic Studies Short Depression Scale (CES-D-10) (29). The CES-D-10 consists of 10 questions each with 4 responses from ‘rarely or none of the time (less than 1 day)’ to ‘all of the time (5-7days)’. Anxiety will be measured using the generalised anxiety disorder scale (GAD-7 scale) which consist of asking caregivers to respond to seven questions around different areas of anxiety they have felt over the previous two weeks, each with four possible responses from ‘Not at all” to “Nearly every day” (30). Resilience will be measured using the Resilience Scale (RS-14) (31) which consist of 14 questions grouped into areas of self-reliance, purpose, equanimity, perseverance, and authenticity. Each question has a response between 1 (strongly disagree) to 7 (strongly agree). Quality of relationship will be measured using the Dyadic Relationship scale (32). This consist of 11 questions measuring the impact of the provision and receipt of family

care. There are four levels of response to each question. Strongly Agree (0) to Strongly Disagree (3). The Parkinsons Disease Questionnaire for carers (PDQ-C) (33) will be used to measure quality of life of carers. The PDQ-C includes 29 questions covering different aspects of caring, with five response scale from 'never' to 'Always'. This is a validated measure for measuring quality of life for carers of persons with Parkinsonism and other related disorders. Self-efficacy will be measured using the General Self-Efficacy scale (34) which consists of 10 questions with 4 responses to each question from 'not at all true' to 'Exactly True'. The positive aspects of caregiving scale (PACS) (35) consists of nine items related to positive aspects of caregiving each with a five response scored Likert scale from 'disagree a lot (1)' to 'agree a lot (5)'. An overall PAC score can be calculated (ranging from 9 to 45) with a higher score reflecting a more positive perception of the caregiving experience. Health related quality of life will be measured using the EuroQol-5 Dimension EQ-5D-5L (36). The EQ- 5D- 5L comprises five domains each assessing a specific dimension of health- related quality of life (mobility, self- care, usual activities, pain and anxiety and depression) with five response levels ('no problems', 'slight problems' 'moderate problems', 'severe problems' and 'extreme problems'. Social care related quality of life will be measured using the ASCOT-Carer SCT4. This is a version of the Adult Social Care Outcomes Toolkit (ASCOT) designed for carers (37) and consists of seven questions focused on areas of quality of life important to carers and sensitive to outcomes of social care services (occupation, control over daily life, self-care, personal safety, social participation and involvement, space and time to be yourself, feeling encouraged and supported). Each question consists of for response options (ideal, no needs, some needs, high-level needs).

As this is a feasibility study we do not intend to report on the secondary outcome results, but rather use these data to determine if these are the correct measures and assessments that would be appropriate to use for an evaluation study of our intervention.

4.7 Data collection

The primary mode of data collection for surveys will be technology mediated. Participants will be sent a personalised link to self-complete questionnaires online which were developed using Qualtrics. Data will be collected at baseline, 3 months after baseline (T1), 6 months after baseline (T2), and 12 months after baseline (T3) (depending on when the participant was recruited into the study). The baseline measures will be collected prior to randomisation and will include demographic data such as age, gender, ethnicity, marital status, sexual orientation, socioeconomic status, education level, carer relationship, usual carer support, length of caring. Where data collection surveys are not completed a reminder will be sent via email to prompt participants to complete. After this, researchers will contact participants and collect data through interview via telephone or internet-based service (e.g. Zoom or Teams). Although effort will be made to obtain follow-up data as close as possible to the relevant timepoints, it is anticipated that there may be some variation. T1, T2, and T3 follow-up will be acceptable up to 2 weeks early and 4 weeks late.

Data will be collected through the iSupport-PD study website, through an electronic case report form (CRF) with data stored on a secure password protected, purposely designed electronic database. Each participant will be randomly assigned a trial identify code at the point of their randomisation for use on CRF forms, electronic database, and other trial documentation. CRF data and electronic forms will be treated as confidential documents and held securely in accordance with regulations. The researcher will make an independent, separate, and confidential, record of participant name, age, date of birth, and trial number to permit identification of all trial participants as needed.

4.8 Data analysis

Analysis of outcome data will be conducted using an intention to treat approach, with patients analysed according to their treatment assignment. It will not be possible to collect outcome data for those who discontinue participation in the study. The data collected from outcome measures will be presented using

summary statistics (number of responses, mean ± standard deviation (SD), percentage frequency) and differences between intervention and control calculated at each follow-up points along with 95% confidence intervals. As this is a feasibility study, it will not be powered to identify significant differences between intervention and control. However, this data will help inform treatment effect estimates and sample size requirements for a larger powered RCT.

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 (38). This will enable interpretation of the findings of the feasibility study and inform whether a larger powered RCT is possible. Progression criteria will be assessed on a traffic light system of green/amber/red zones (39). Successful outcome of the feasibility trial would be to have all criteria assessed as green zones, suggesting no adjustments would be required for a future RCT. It is anticipated that progression to a future RCT would still be possible with a combination of amber and green zones but with potential adjustments implemented to mitigate risks highlighted in this feasibility study. Any red zone criteria would indicate that either the RCT trial design, or processes, will need to be overhauled for any future definitive study. All thresholds have been set based on levels that would enable completion of the trial objectives (Green without adaptation, Amber with adaptations to trial processes, Red/stop would not be possible to complete):

Criteria	**Green**	**Amber**	**Red**
Recruitment of participants based on target of n=100	>75 (75%)	50 - 74 (50 - 74%)	<=50 (<50%)
Intervention engagement: assessed by number of intervention participants who have used iSupport-PD	>=70%	50-69%	50%
Recruited participants completing 3-month follow-up	>=75%	50-74%	<50%.
Recruited participants completing 6-month follow-up	>=75%	50-74%	<50%.
Recruited participants completing 12-month follow-up	>=75%	50-74%	<50%.
Ability to collect outcome data (assessed on baseline and follow-up). Each outcome measure would be a candidate for removal in a larger RCT if less than 85% of participants attempt to complete a measure:	>=85%	70-84%	<70%.

In addition, data around the use of the iSupport-PD intervention for those in the intervention arm will be analysed and reported to identify potential barriers to participants in accessing the intervention. This may include information such as number of times iSupport-PD is accessed, time spent on each page, number of contacts with technical support.

5. 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. Resources utilised in the intervention and control group are anticipated to include factors such as cost of iSupport-PD, primary care, secondary care, and public and private social care. Resource use data will be collected from participant follow-up forms and expert opinion. Appropriate unit costs to be applied to resource use will be identified from a combination of local costings and national databases. 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, 3,6,12 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. For example, data will be bootstrapped to account for the expected skewness evident in economic cost data. The data collected as part of this feasibility study could be used to inform subsequent pre-trial modelling.

6. Process evaluation

Alongside the feasibility study, a process evaluation will be conducted in line with MRC guidance for process evaluation of complex interventions and the new MRC framework for developing and evaluating complex interventions (20). 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 ages, genders, carer relationships, caring experiences, ethnic groups, and socioeconomic status, as well as carers with different patterns of intervention usage (e.g. high and low users) and across different trial arms and recruitment methods (e.g. NHS, Parkinson's UK). On recruitment, trial participants will be asked for their consent to be contacted by the research team about the interview study and they will provide the demographic data required for the purposive sampling.

Participants will be offered either a telephone or teams interview at time convenient for them. Interviews will be audio recorded and transcribed verbatim. 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. Topic guides will be driven by our initial programme theories and will explore potentially unintentional intervention outcomes (e.g. further exacerbating carer strain). Data collection will cease once data saturation is met and the research team are confident that they have recruited participants with a range of demographics and sufficient participants from underserved groups. Interviews will be audio-recorded and transcribed verbatim. Transcribing will either be completed by the researcher or by McGowan Transcriptions (a secure system that researchers at Southampton University have a confidentiality agreement with). Once downloaded the audio recording will be deleted. The transcript will then be anonymised, and any personal identifiers removed from transcripts. Transcripts will be saved onto a secure university account. Inductive reflexive thematic analysis will be carried out (40) to further refine our programme theory and identify future intervention modifications.

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.

7. Assessment of safety

We do not anticipate any adverse events as part of this intervention which consists of guidance and support in addition to usual care. However, we will collect information from participants including hospital admissions and other NHS and social care resource use. As this is a feasibility trial, no data monitoring committee will be used. However, once the feasibility trail (WS2) begins recruitment, there will be a update of trial progress and

discussion of any unanticipated harms that may occur with consideration of ongoing trial safety.

8. Project Management

8.1 Trial management group

A Trial Management Group (TMG) composed of research members will oversee the feasibility trial. Members will include the Chief Investigators, trial manager, health economist etc.

TMG will meet frequently during both the set-up and running of the trial. Once the trial begins, TMG will monitor the different aspects of the trial such as recruitment, and data collection. They will also ensure that trial protocol is followed.

8.2 Patient and public involvement

We will work in partnership with carers and people with Parkinson's, to improve the relevance, quality, and impact of the iSupport-PD feasibility study. We have also involved a PPI advisory panel, with the PPI lead (JM) being a member of the research team. The PPI team consist of care partners of people with Parkinson's and have a range of experience. The PPI team have advised on the iSupport-PD design. In addition, for WS2 and WS3 they have been involved in co-production of data collection materials and approaches to recruitment.

All study participants will be offered a £10 gift voucher at the end of the study as a thank you for taking part. Each participant that is interviewed will also receive an additional £10 voucher as a thank you for taking part.

Any updates on our study will posted on our study website https://hosting.northumbria.ac.uk/isupportpd/, which is available to the public.

9. Ethics and regulatory approvals

Ethical approval will be sort by Northumbria University and the NHS REC.

10 Monitoring

10.1 Quality assurance and Quality Control of data

Trial processed and data will be monitored throughout the trial with updated provided monthly at the trial management group meetings. Data collected during the course of the trial will be checked during the trial to offer quality assurance. As this is a feasibility trial, quality assurance will also allow the team to assess issues such as incomplete data collection forms, which may suggest misunderstanding, unwillingness to complete certain questions, or misunderstanding of data collection forms. This will contribute to the findings of the feasibility study and allow flexibility and changes to trial processes during the trial (with changes to the protocol noted and ethical approval for adjustments sought where necessary.

10.2 Monitoring plan

A Monitoring Plan will be prepared prior to participant recruitment detailing the monitoring strategy for the feasibility study and corresponding cost-effectiveness analysis (WS2 and WS3). The plan will include requirements for day-to-day centralised monitoring of the trial and any additional safety requirements.

10.3 Study end date

Study end date, defined as the last point of data collection, will be 31st October 2025. No further data collection will occur after this point and the data will be 'locked' to allow final analysis. The Research Ethics Committee will be notified of the study end date within 90 days. Following study end date, the final report will be submitted to the Research Ethics Committee within 12 months of the end of study.

10.4 Confidentiality

Names and contact information will be held securely on password protected computer/servers. Participants will be given a unique participant trial identification (ID) number. This ID will be held in a separate secure file with access on a need-by-need basis only within the study team. A separate master file will be constructed linking participants to their unique trial identification number and will be kept secure at all times with access limited within the study team to the Chief investigators and trial statistician, others who require access will be determined on a case-by-case basis. Data for the feasibility study will be collected through the iSupport-PD study website, through an electronic case report form (CRF) with data stored on a secure password protected, purposely designed electronic database.

Transcripts will be anonymised and any potentially identifying information will be removed. The interview recordings will be destroyed once they are transcribed and checked. Transcription will be carried out by a member of the research team. The research team will not have details of who has been invited unless they express an interest to the research team.

Participants are free to withdraw at any point during the trial without any impact on their future health and care. Unless specifically withdrawn, participant data will be used up until the point of withdrawal.

11. Pathways to impact

We plan to disseminate our findings through presentations at national and international social care and occupational therapy conferences, and we will submit findings for publication in a peer-reviewed academic journal. In addition, plain English summaries of the results will be coproduced with the PPI members and results disseminated in accessible formats. Within 6 months of study completion, participants will be offered an accessible summary of the study findings. In addition, the wider public will be informed through press releases or blogs linked to dissemination events to ensure a high level of awareness of our work in the media (e.g. Parkinson's awareness month, Carers Week) and give talks at PD support groups. The PPI lay advisory group, Parkinson's UK and Carers Trust will disseminate information via their website and social media accounts. Throughout the project, a dedicated 'iSupport-PD' project webpage and social media account that will give regular updates on the research progress to keep participants, stakeholders, and the academic community updated.

References

1. UK Ps. The prevalence and incidence of Parkinson's in the UK. 2018.
2. Laperle AH, Sances S, Yucer N, Dardov VJ, Garcia VJ, Ho R, et al. iPSC modeling of young-onset Parkinson's disease reveals a molecular signature of disease and novel therapeutic candidates. Nat Med. 2020;26(2):289-99.
3. Chaudhuri KR, Yates L, Martinez-Martin P. The non-motor symptom complex of Parkinson's disease: a comprehensive assessment is essential. Curr Neurol Neurosci Rep. 2005;5(4):275-83.

4. Watson GS, Leverenz JB. Profile of cognitive impairment in Parkinson's disease. Brain Pathol. 2010;20(3):640-5.
5. Aarsland D, Brønnick K, Larsen JP, Tysnes OB, Alves G. Cognitive impairment in incident, untreated Parkinson disease: the Norwegian ParkWest study. Neurology. 2009;72(13):1121-6.
6. Aarsland D, Andersen K, Larsen JP, Lolk A, Kragh-Sørensen P. Prevalence and characteristics of dementia in Parkinson disease: an 8-year prospective study. Arch Neurol. 2003;60(3):387-92.
7. Hand A, Oates LL, Gray WK, Walker RW. The role and profile of the informal carer in meeting the needs of people with advancing Parkinson's disease. Aging Ment Health. 2019;23(3):337-44.
8. Hand A, Oates LL, Gray WK, Walker RW. Understanding the Care Needs and Profile of People Living at Home With Moderate to Advanced Stage Parkinson Disease. J Geriatr Psychiatry Neurol. 2018;31(5):237-47.
9. Hand A, Oates LL, Gray WK, Dismore LL, Baker K, Naisby J, et al. Understanding Caregiver Strain in Parkinsonism-A Mixed Methods Approach. J Geriatr Psychiatry Neurol. 2022;35(3):363-73.
10. Klaptocz J, Gray WK, Marwood S, Agarwal M, Ziegler J, Webb Z, et al. The Pattern of Hospital Admissions Prior to Care Home Placement in People With Parkinson's Disease: Evidence of a Period of Crisis for Patients and Carers. J Aging Health. 2019;31(9):1616-30.
11. Care DoHaS. The Government's Mandate to NHS England for 2018-19. London; 2019.
12. Excellence NIfHaC. Supporting adult carers. NICE guidance [NG150]. 2020.
13. Al-Janabi H, McLoughlin C, Oyebode J, Efstathiou N, Calvert M. Six mechanisms behind carer wellbeing effects: A qualitative study of healthcare delivery. Social Science & Medicine. 2019;235:112382.
14. Foley A, Powell, A., Foster, D. Informal carers. Commons Library Research Breifing; 2021.
15. González-Fraile E, Ballesteros J, Rueda JR, Santos-Zorrozúa B, Solà I, McCleery J. Remotely delivered information, training and support for informal caregivers of people with dementia. Cochrane Database Syst Rev. 2021;1(1):Cd006440.
16. Teles S, Paúl C, Lima P, Chilro R, Ferreira A. User feedback and usability testing of an online training and support program for dementia carers. Internet Interventions. 2021;25:100412.
17. Dickinson C, Dow J, Gibson G, Hayes L, Robalino S, Robinson L. Psychosocial intervention for carers of people with dementia: What components are most effective and when? A systematic review of systematic reviews. Int Psychogeriatr. 2017;29(1):31-43.
18. Yardley L, Morrison L, Bradbury K, Muller I. The person-based approach to intervention development: application to digital health-related behavior change interventions. J Med Internet Res. 2015;17(1):e30.
19. O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, et al. Guidance on how to develop complex interventions to improve health and healthcare. BMJ Open. 2019;9(8):e029954.
20. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ. 2021;374:n2061.
21. Muller I, Rowsell A, Stuart B, Hayter V, Little P, Ganahl K, et al. Effects on Engagement and Health Literacy Outcomes of Web-Based Materials Promoting Physical Activity in People With Diabetes: An International Randomized Trial. J Med Internet Res. 2017;19(1):e21.
22. Tuijt R, Tan A, Armstrong M, Pigott J, Read J, Davies N, et al. Self-Management Components as Experienced by People with Parkinson's Disease and Their Carers: A Systematic Review and Synthesis of the Qualitative Literature. Parkinsons Dis. 2020;2020:8857385.
23. Chan A-W, Tetzlaff JM, Altman DG, Dickersin K, Moher D. SPIRIT 2013: new guidance for content of clinical trial protocols. The Lancet. 2013;381(9861):91-2.
24. Thomas AJ, Taylor JP, McKeith I, Bamford C, Burn D, Allan L, et al. Revision of assessment toolkits for improving the diagnosis of Lewy body dementia: The DIAMOND Lewy study. International Journal of Geriatric Psychiatry. 2018;33(10):1293-304.
25. Russell D, Hoare ZS, Whitaker R, Whitaker CJ, Russell IT. Generalized method for adaptive randomization in clinical trials. Stat Med. 2011;30(9):922-34.
26. Pot AM, Gallagher-Thompson D, Xiao LD, Willemse BM, Rosier I, Mehta KM, et al. iSupport: a WHO global online intervention for informal caregivers of people with dementia. World Psychiatry. 2019;18(3):365-6.

27. Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. Stat Methods Med Res. 2016;25(3):1057-73.
28. Bédard M, Molloy DW, Squire L, Dubois S, Lever JA, O'Donnell M. The Zarit Burden Interview: a new short version and screening version. Gerontologist. 2001;41(5):652-7.
29. Radloff LS. The CES-D Scale:A Self-Report Depression Scale for Research in the General Population. Applied Psychological Measurement. 1977;1(3):385-401.
30. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006;166(10):1092-7.
31. Wagnild G. A review of the Resilience Scale. J Nurs Meas. 2009;17(2):105-13.
32. Sebern MD, Whitlatch CJ. Dyadic Relationship Scale: A Measure of the Impact of the Provision and Receipt of Family Care. The Gerontologist. 2007;47(6):741-51.
33. Jenkinson C, Dummett S, Kelly L, Peters M, Dawson J, Morley D, et al. The development and validation of a quality of life measure for the carers of people with Parkinson's disease (the PDQ-Carer). Parkinsonism & Related Disorders. 2012;18(5):483-7.
34. Schwarzer R, Jerusalem M. Generalized self-efficacy scale. J Weinman, S Wright, & M Johnston, Measures in health psychology: A user's portfolio Causal and control beliefs. 1995;35(37):82-003.
35. Tarlow BJ, Wisniewski SR, Belle SH, Rubert M, Ory MG, Gallagher-Thompson D. Positive Aspects of Caregiving:Contributions of the REACH Project to the Development of New Measures for Alzheimer's Caregiving. Research on Aging. 2004;26(4):429-53.
36. Hernández Alava M, Pudney S, Wailoo A. Estimating the Relationship Between EQ-5D-5L and EQ-5D-3L: Results from a UK Population Study. PharmacoEconomics. 2023;41(2):199-207.
37. Rand SE, Malley JN, Netten AP, Forder JE. Factor structure and construct validity of the Adult Social Care Outcomes Toolkit for Carers (ASCOT-Carer). Quality of Life Research. 2015;24(11):2601-14.
38. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239.
39. Avery KN, Williamson PR, Gamble C, O'Connell Francischetto E, Metcalfe C, Davidson P, et al. Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. BMJ Open. 2017;7(2):e013537.
40. Braun V, Clarke V, Hayfield N, Terry G. Thematic Analysis. In: Liamputtong P, editor. Handbook of Research Methods in Health Social Sciences. Singapore: Springer Singapore; 2019. p. 843-60.