**Personalised Care for People with Parkinson's Disease: PD-Care**
**Process Evaluation Statistical Analysis Plan**
Version 1.0
26 November 2024

# 1 Introduction

## 1.1 Purpose and scope of the statistical analysis plan

This statistical analysis plan (SAP) describes the statistical analyses for the parallel process evaluation for the PD-Care randomised control trial. This document should be read alongside the main trial statistical analysis plan v1.3. Participants were randomly selected to treatment as usual (control arm) and the 'Live Well with Parkinson's' toolkit (intervention arm). Participants randomised to the intervention arm were given access to the toolkit for a 6-month period, to use with/without a 'supporter'. Supporters are members of the research team with a non-specialist background and who were trained on intervention contents and behaviour change techniques. Supporters contacted participants either in-person, virtually or via telephone to talk through the different sections in the toolkit and guide them through the toolkit usage and support goal setting using behavioural techniques, such as motivational interviewing and action-planning. Each participant was offered a maximum of 6 supporter-led sessions as follows:
Session 1: within 2 weeks of baseline assessments
Session 2: about 2 weeks after session 1
Sessions 3-6: about 4 weeks after the previous session

After each session, the supporter completed a session checklist (see appendix 1 for a copy of checklists used – session 1 checklist, session 2 checklist, session 3 onwards checklist and final session checklist)

## 1.2 Protocol version

Full details of the trial design, population, intervention, comparison and outcome variables may be found in the protocol (version 1.4 dated 23/03/2023).

## 1.3 Trial registration

The trial is registered with the ISRCTN registry (https://doi.org/10.1186/ISRCTN92831552).

## 1.4 Authorship

This SAP has been written by Tasmin Rookes (TR), based on the main trial SAP written by Mariam Adeleke and Gareth Ambler.

# 2 Trial Summary

## 2.1 Title

Personalised care for people with Parkinson's Disease: PD-Care – Process Evaluation

## 2.2 Aims

The mixed methods process evaluation aims to understand participants perspective of taking part in the study, analyse the fidelity of intervention delivery, and explore the mechanisms of impact behind any intervention effects.

These will be achieved through:

1. Surveying participants in the intervention group
2. Semi-structured interviews with participants, their carers, and supporters
3. Fidelity checklist analysis to assess fidelity, adherence, and engagement
4. Assessing reach
5. Assessing mechanisms of impact on the trial outcome, through self-efficacy, patient activation, and goal progress

## 2.3 Population

Community-dwelling people with Parkinson's disease.

## 4.4 Inclusion criteria

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

## 4.4 Exclusion criteria

- Atypical Parkinsonism
- Currently an inpatient or living in a care home
- Lack of capacity to take part MoCA <11
- Life expectancy <6months

# 3 Study Methods

## 3.1 Design

A multi-centre, single blind trial, parallel group, two arm, randomised controlled trial to assess the clinical and cost effectiveness of PD-Care in people with Parkinson's disease with a 6-month internal pilot. A mixed-method process evaluation using trial data, quantitative, and qualitative feedback data to explore fidelity, engagement, mechanisms of impact, and acceptance.

## 3.2 Intervention

The usual care plus training and access to PD-Care, supported by trained service providers (nurses not involved in delivering usual care to prevent contamination of the control arm) for up to 6 sessions.

## 3.3 Comparison

The usual care from existing sources (GP, PD specialist service +/- NHS PD Nurse Specialist).

## 3.4 Sample

Questionnaire: All intervention participants who had not withdrawn
Qualitative interviews: Purposively sampled intervention participants based on age, gender, ethnicity, age left education, disease severity, cognition, rurality, toolkit use, number of sessions attended, and carer involvement (methods reported elsewhere)
Reach: All trial participants compared to those approached and declined or ineligible

# 4 Statistical Principles

## 4.1 Organisation of data and analyses

Prior to performing analyses, basic checks will be performed by the statisticians on the blinded data prior to database lock to ensure accuracy. Each outcome (primary and secondary) variable and baseline demographic variable will be checked for:

- missing values
- values outside an acceptable range
- other inconsistencies

If missing values or other inconsistencies are found, the corresponding data will be sent to the Trial Manager for checking and will either be corrected, deemed to be missing or confirmed correct, as appropriate.

## 4.2 Confidence intervals and p-values

All statistical tests will be two-sided. All estimates will be presented with two-sided 95% confidence intervals.

## 4.3 Analysis populations

The 'intention-to-treat' population will include all randomised patients according to the treatment to which they were randomised to receive. Any patients that have withdrawn from the trial, and withdrawn permission to keep and use their data, will be necessarily excluded.

## 4.4 Adherence

Participants in the intervention arm will be categorised into different groups of adherence based on the number of sessions they attended combined with the number of times they self-reported independent use of the toolkit in between sessions.
Adherence categories are shown below:

- High adherence – Attended at least 4 sessions and used the toolkit in between at least 3 sessions
- Moderate adherence - Attended at least 4 sessions and used the toolkit in between 1 or 2 sessions
- Medium adherence – Attended at least 4 sessions, but did not use the toolkit independently OR attended 3 sessions and used the toolkit in between 1 or 2 sessions
- Low adherence – Attended 1 or 2 sessions, irrespective of independent use, OR attended 3 sessions with no independent use between sessions
- Non-adherent – Did not attend any sessions or use the toolkit independently

## 4.5 Goal Progress

Goal progress was recorded in three ways. The first was self-rated progress the participants felt they had made towards their goals. This was rated as, none, a little, somewhat, good, and excellent. On a scale of 1 to 10, participants then rated how much they felt this progress was due to the toolkit itself, and how much was due to the sessions with the 'Live Well' supporter. This was recorded in the final session with the supporter and documented within the final session fidelity checklist and in the GP summary that was sent to participants GPs when they had completed the intervention.

Goals will be categorised into the 7 goal types outlined in a previous qualitative systematic review [1]. The 7 goal types are (1) medication management, (2) physical exercise, (3) self-monitoring techniques, (4) psychological strategies, (5) maintaining independence, (6) encouraging social engagement, and (7) providing knowledge and information. If a goal cannot fit into these categories, then we will have an 'other category'.

# 5 Trial Population

## 5.1 Recruitment, retention, and reach

To assess reach we will explore the number of people approached, recruited, ineligible, and declined, which will be descriptively summarised.

As part of a study within a project (SWAP) we are exploring the demographics of our sample in comparison to the national sample, to see if we recruited a representative sample as part of the trial. We will also explore differences in retention within subgroups. This is reported in a separate SAP: 'Recruiting underserved communities to a self-management intervention for people with Parkinson's (PD-Care SWAP)'.

## 5.2 Variables

Categorical variables will be reported as counts and percentages. Continuous variables will be summarised as means and standard deviations (SD) or medians and interquartile ranges as appropriate depending on the distribution of the data.

Measures and variables included in this analysis include:

- The primary outcome (PDQ-39)
- Patient Activation Measure (PAM)
- Self-efficacy
- Self-rated goal progress
- Supporter completed and independent fidelity checklist ratings
- Intervention participants feedback questionnaire responses
- Qualitative interviews with participants (methods reported elsewhere)
- Trial documentation: recruitment trackers
- Digital analytics from the online intervention toolkit

# 6 Statistical analysis plan

## 4.4 Primary outcome

The primary outcome is Parkinson's Disease Questionnaire (PDQ-39) score at 12 months.

## 6.2 Fidelity

**Research question: Was there fidelity of intervention delivery i.e., was the intervention delivered to participants as intended?**

Fidelity checklists were completed by supporters who delivered the intervention at each session with the participants. This approach was taken following a systematic review exploring the approaches to assessing fidelity in self-management interventions for people with long term conditions. Checklists included items such as, independent use of the toolkit between sessions, reviewing goal progress, signposting to information, and use of behaviour change techniques. Answers could be Yes, Somewhat, or No. The checklists are available in appendix 1.

To check accuracy of checklist completion by those delivering the intervention, 10% of participants who had at least three sessions recorded (to ensure a complete enough dataset for comparison) will be randomly selected, and the audio/video recordings of their sessions will be independently rated by two researchers. An initial pilot will be conducted with one participant's sessions, with at least three team members independently completing the fidelity checklists. These will be compared, and any disagreements discussed to create a framework for independently completing the other checklists. Two researchers will then independently complete the checklists for the remaining participants, with input from the wider team to resolve discrepancies.

For the analysis, responses of Yes and Somewhat will be coded as 1 and responses of No will be coded as 0. Fidelity will be calculated as a percentage, with the number of responses as Yes or Somewhat divided by total number of response options. Sessions will be summarised as first, second, subsequent (up to four), and final, as the checklist items were different for each session and not all participants had the same number of sessions.

We will conduct an intraclass correlation coefficient analysis to determine the agreeability between the supporter and independent ratings. We will consider an ICC score of 0.75-0.9 as good reliability and above 0.9 as excellent reliability. If they are reliable then we will explore fidelity for the whole sample, using the supporter completed ratings for all intervention participants. Fidelity scores 60%-79% will be good fidelity and 80% or above will be considered excellent fidelity.

## 6.3 Adherence to the intervention

**Research question: What is the impact of adherence to the intervention (independent use and session attendance) on the primary outcome (PDQ-39)?**

We will conduct secondary regression analyses exploring the relationship between adherence to the intervention (session attendance and independent toolkit use) and the primary outcome (PDQ-39) and goal progress.

In the intervention group only, using the 5 categories outlined in section 4.4 we will conduct ordinal regression analysis. We will then dichotomise these 5 categories into 2 groups (high and moderate vs. medium, low, and none) and conduct logistic regression analysis. Our full model will include participant characteristic variables such as age, gender, ethnicity, deprivation, education, cognition, and disease severity. This will enable us to explore whether demographic characteristics correlate with adherence to the intervention and/or self-reported independent usage of toolkit components.

We will then conduct exploratory analyses comparing the two groups to explore the effect of the intervention on the primary outcome based on adherence categories e.g., a complier average causal effect analysis and/or conduct mixed model regression including the PDQ-39 scores and the adherence categories with an interaction term between the intervention group variables to enable estimation of the intervention effect at 12 months depending on if participants adhered to the intervention or not.

## 6.4 Mechanisms of Impact – PAM and Self-efficacy

**Research question: What is the impact of the PAM and self-efficacy on the primary outcome (PDQ-39)?**

In the intervention group, we will conduct multiple linear regression analyses exploring the relationship between baseline PAM and self-efficacy scores and the primary outcome (PDQ-39). Our full model will include participant characteristic variables such as age, gender, ethnicity, deprivation, education, cognition, and disease severity. We will also conduct mixed model regression including the PDQ-39 scores and baseline PAM and self-efficacy scores with an interaction term between the intervention group variables.

## 6.5 Mechanisms of Impact – Goal Progress and Goal Type

**Research question: What is the impact of goal progress and goal type on the primary outcome (PDQ-39)?**

In the intervention group, we will conduct ordered logistic regression analyses exploring the relationship between goal progress and goal type categories and the primary outcome (PDQ-39). Our full model will include participant characteristic variables such as age, gender, ethnicity, deprivation, education, cognition, and disease severity. We will also conduct mixed model regression including the PDQ-39 scores and goal progress categories with an interaction term between the intervention group variables. For those in the control group, there goal progress will be marked as 0 - no progress.

## 6.6 Mechanisms of Impact – Toolkit use

**Research question: Which aspects of the toolkit did people engage with and when (both self-report and digital analytics)?**

Using data collected by the supporters as part of the fidelity checklists, we will descriptively summarise number of participants independently using the toolkit after each session, which aspects of the toolkit participants used, time spent using the toolkit in between sessions, and carer involvement. These will be descriptively analysed.

### Digital toolkit

We will explore which aspects of the toolkit participants used and when. This analysis will explore the subgroup of participants who used the digital toolkit. We will descriptively summarise how many participants accessed each of the seven toolkit sections and the frequency they accessed these sections. We will also describe use within the 6-month intervention window and the 6-months following the intervention period.

For the information pages, we will descriptively summarise the number of page views within the intervention window (January 2022 till July 2024). In addition, we will summarise the number of views of the videos we created of the content in the information pages. Data is not available for individual page views, so we will not be able to explore differences in characteristics between those who viewed different information pages.

## 6.7 Acceptability and Context

To determine acceptability and the impact of context, all intervention participants were sent a feedback questionnaire, 2-4 weeks after completing the intervention, asking them about the perceived helpfulness of and satisfaction with the intervention, how likely they were to use the toolkit in the future, along with two open ended questions asking about positive aspects of and suggested improvements for the intervention (available on request). Positive responses (helpful, very helpful) above 60% were considered acceptable, in line with the kappa boundaries. When including the 'slightly helpful' response option, this was increased to 80%, to be more conservative. Qualitative open-ended questions were synthesised using content analysis, with a focus on areas for improvement and positive impacts of the intervention.

# 7 Appendix

## 7.1 Fidelity checklists

**Appointment Checklist: session one**

**Enter a cross x in the YES, A bit or No column for each activity**

| **Participant ID:** | **Date:** |
|---|---|

Before session

- Explored the toolkit and manual in detail
- Appointment time booked
- Check participant is happy with use of video conferencing
- Confirm that the baseline assessments and consent have been completed

Start of each session

- Consent to recording and switched on
- Explore whether the participant would like a supportive other to join the sessions and how they would like them to be involved

| **Summary** | **Appointment Activity** | **YES** | **Somewhat** | **No** |
|---|---|---|---|---|
| **Introduction** | The purpose of the toolkit and session one was explained? | | | |
| | An overview of the toolkit was given with explanation of their uses? | | | |
| | Have they accessed the toolkit? If yes, how long (duration in minutes) did they spend on the toolkit?: | | | |
| | | | | |
| **Carer** | Is a carer attending this session with the participant? | | | |
| | | | | |
| **My health** | Did you and the participant complete the About me & My health sections? | | | |
| | | | | |
| **Information** | Does the participant have any concerns right now? (if no ask them to have a think about this before their next session) | | | |

| | | | | |
|---|---|---|---|---|
| | What sections were they directed to: | | | |
| | | | | |
| **My Wellbeing /behaviour change techniques (BCTs)** | Introduce the concept of the My Wellbeing section | | | |
| | Discuss the 'What I am already doing' questions, asking the participant to enter key points. | | | |
| | **Did you use any of the following for this session?** | | | |
| | Motivational interviewing/building motivation (p31 of the intervention manual) | | | |
| | Any other BCTs: | | | |
| | | | | |
| **Symptom review / Set an action** | Was the My Symptom's section covered or if not the participant has agreed to do it before the next session? | | | |
| | If My Symptom's section completed in session, was another task set to complete before the next session?<br>TASK: | | | |
| | | | | |
| **Notes** | (e.g., what hasn't been covered and what to focus on next time, any priorities identified) | | | |

**End of appointment**

- The next appointment was arranged (ideally around 2 weeks) –
- Upload audiofile and checklist sent to Data Safe Haven and delete from personal devices -

| **Appointment Checklist: Session two**<br>**Enter a cross x in the Yes, somewhat or No column for each activity** | |
|---|---|
| **Participant ID:** | **Date: /2023** |

Before session

- Appointment time booked, check participant is happy with use of video conferencing, confirm that the baseline assessments and consent have been completed

Start of each session

- Consent to recording and switched on
- Explore whether the participant would like a supportive other to join the sessions and how they would like them to be involved

| Summary | Appointment Activity | Yes | Somewhat | No |
|---|---|---|---|---|
| **Re-Introduction** | Brief reintroduction of you, the study and the toolkit was conducted? | | | |
| | Did you provide any trouble shooting advice with the toolkit? | | | |
| | | | | |
| **Carer** | Is a supportive other attending this session? | | | |
| | Have they shared the toolkit with their supportive other? | | | |
| | | | | |
| **Progress review/** | Did the participant access the toolkit since the last session? Add to notes any detail. | | | |
| **Information** | If accessed, how long (duration in minutes) did they spend independently since last session?: | | | |
| | Did the participant complete the actions agreed from the previous session? | | | |
| | Discuss symptom pack (found in My Information) and highlight advice on the pages | | | |
| | Do they have any concerns right now that can be explored in the information sections? | | | |
| | What sections were they directed to: | | | |
| | | | | |
| **Explore the 'wellbeing' section of the toolkit** | Has the 'Daily life' section has been discussed and completed? | | | |
| | Has the participant identified priorities and ideas? | | | |
| | Has the 'What next' section been completed along with 'back-up' plans? | | | |
| | Has the progress section of the toolkit has been discussed and encouraged? | | | |

| Summary | Appointment Activity | Yes | Somewhat | No |
|---|---|---|---|---|
| | Have sections that facilitate recording (Tracker, Notes and To-do-Lists) been demonstrated? | | | |
| | | | | |
| **Behaviour change techniques** | **Have any of the following been used?** | | | |
| | Motivational interviewing/building motivation (p31 of the intervention manual) | | | |
| | Forming habits (p44) | | | |
| | Giving positive feedback (p42) | | | |
| | Other: | | | |
| | | | | |
| **Notes** | (e.g., what hasn't been covered and what to focus on next time, any priorities identified) | | | |

**End of appointment**

- The next appointment was arranged
- Upload audiofile and checklist sent to Data Safe Haven and delete from personal devices

| **Appointment Checklist: Session three onwards**<br>**Enter a cross x in the YES, Somewhat or NO column for each activity** | |
|---|---|
| **Participant ID:** | **Date:** |

**Before session**

- Appointment time booked, Check participant is happy with use of video conferencing, Confirm that the baseline assessments and consent have been completed

**Start of each session**

- Consent to recording and switched on
- Explore whether the participant would like a supportive other to join the sessions and how they would like them to be involved

| Summary | Appointment Activity | YES | Somewhat | NO |
|---|---|---|---|---|
| **Re-Introduction and process** | Explore how they have been getting on with the toolkit? | | | |
| | Did you provide any trouble shooting advice with the toolkit? | | | |
| | | | | |
| **Carer** | Is a supportive other attending this session? | | | |
| | Have they shared the toolkit with their supportive other? | | | |
| | | | | |
| **The Wellbeing section** | A priority/idea has been identified or had previously identified one at previous session | | | |
| | Explore how they are getting on with their idea/steps (use the reflect section) | | | |
| | Has the participant been recording their progress? | | | |
| | Do they feel ready to pursue another idea or update their idea? (only if appropriate) | | | |
| | | | | |
| **Behaviour change techniques** | **Have any of the following been used:** | | | |
| | Motivational interviewing/building motivation (p31 of the intervention manual) | | | |
| | Forming habits (p44) | | | |
| | Problem solving (p35) | | | |
| | Giving positive feedback (p41) | | | |
| | Coping with setbacks (p43) | | | |
| | Other: | | | |
| | | | | |
| **Checklist of toolkit use** | **Since the last session has the participant used:** | | | |
| | Did the participant access the toolkit since the last session? | | | |
| | The information pages? | | | |
| | About me? | | | |

| Summary | Appointment Activity | YES | Somewhat | NO |
|---|---|---|---|---|
| | My Health? | | | |
| | My Wellbeing section? | | | |
| | Symptom review? | | | |
| | My Tracker? | | | |
| | Calendar or to-do lists? | | | |
| | If accessed, how long (duration in minutes) did they spend independently since last session?: | | | |
| | | | | |
| **My Tracker** | If The tracker has not been used, a demonstration was given on how it might be useful? | | | |
| **Symptom review** | Reminded participants this can be updated as symptoms change | | | |
| **Peer support** | The peer support/PUK section was highlighted and discussed? | | | |
| | | | | |
| **Notes** | (e.g., what hasn't been covered and what to focus on next time, any priorities identified) | | | |

**End of appointment**

- The next appointment was arranged -
- Upload audiofile and checklist sent to Data Safe Haven and delete from personal devices -

| **Appointment Checklist: Final appointment**<br>**Enter a cross x in the YES, Somewhat or NO column for each activity** | |
|---|---|
| **Participant ID:** | **Date:** |
| | |

| Summary | Appointment Activity | YES | Somewhat | NO |
|---|---|---|---|---|
| **Re-Introduction and process** | Explore how they have been getting on with the toolkit? | | | |
| | Did you provide any trouble shooting advice with the toolkit? | | | |
| | | | | |
| **Carer** | Is a supportive other attending this session? | | | |
| | Have they shared the toolkit with their supportive other? | | | |
| | | | | |
| **The Wellbeing section** | A priority/idea has been identified or had previously identified one at previous session | | | |
| | Explore how they are getting on with their idea/steps (use the reflect section) | | | |
| | Has the participant been recording their progress? | | | |
| | Do they feel ready to pursue another idea or update their idea? (only if appropriate) | | | |
| | | | | |
| **Behaviour change techniques** | **Have any of the following been used:** | | | |
| | Motivational interviewing/building motivation (p31 of the intervention manual) | | | |
| | Forming habits (p44) | | | |
| | Problem solving (p35) | | | |
| | Giving positive feedback (p41) | | | |
| | Coping with setbacks (p43) | | | |
| | Other: | | | |
| | | | | |
| **Checklist of toolkit use** | **Since the last session has the participant used:** | | | |
| | Did the participant access the toolkit since the last session? | | | |
| | The information pages? | | | |
| | About me? | | | |

| Summary | Appointment Activity | YES | Somewhat | NO |
|---|---|---|---|---|
| | My Health? | | | |
| | My Wellbeing section? | | | |
| | Symptom review? | | | |
| | My Tracker? | | | |
| | Calendar or to-do lists? | | | |
| | If accessed, how long (duration in minutes) did they spend independently since last session?: | | | |
| | | | | |
| **My Tracker** | If The tracker has not been used, a demonstration was given on how it might be useful? | | | |
| **Symptom review** | Reminded participants this can be updated as symptoms change | | | |
| **Peer support** | The peer support/PUK section was highlighted and discussed? | | | |
| | | | | |
| **Final appointment only** | Discussed how participant can use what they have learnt independently going forward<br>(ask about their future plans to self-manage and live well with Parkinson's) | | | |
| | If ongoing support is needed then check participant has contact details of where can seek support from (e.g., PUK advisor etc.). N/A | | | |
| | GP Summary discussed and completed. (Consent gained for summary to be sent to GP.) | | | |
| | | | | |
| **Notes** | (e.g., what hasn't been covered, how to support the maintenance of the existing priorities ) | | | |
| | <u>Overall you felt your progress towards achieving your priorities was (please circle)</u><br>None at all A bit Somewhat Good Excellent (fully achieved) | | | |

| Summary | Appointment Activity | YES | Somewhat | NO |
|---|---|---|---|---|
| | How much, if any, progress or improvement made towards your goals, ideas or wellbeing is due to the following:<br>a. Toolkit (where 0 is not at all, 5 moderately and 10 is completely) = **/10**<br>b. Supporter sessions = **/10**<br>**Please add reasons for each here:** | | | |
| **End of appointment**<br>• Upload audiofile and checklist sent to Data Safe Haven and delete from personal devices<br>• If participant consents, GP summary to be completed and sent | | | | |

## 7.2 List of Abbreviations

| | | | |
|---|---|---|---|
| AE | Adverse Event | MOCA | Montreal Cognitive Assessment test |
| AR | Adverse Reaction | NICE | The National Institute for Health and Care Excellence |
| CACE | Complier Average Cause Effect | NMSS | Non-Motor Rating Scale |
| CI | Chief Investigator | PD | Parkinson's disease |
| CRF | Case Report Form | PI | Principle Investigator |
| CRO | Contract Research Organisation | PD-QOL | Parkinson's disease quality of life |
| CSRI | Client Service Receipt Inventory-shortened, adapted for PD | PIS | Participant Information Sheet |
| DMC | Data Monitoring Committee | QA | Quality Assurance |
| EQ-5D-5L | Quality of life measure | QALY | Incremental cost per quality adjusted life year |
| GCP | Good Clinical Practice | QC | Quality Control |
| GDPR | General Data Protection Regulation | RCT | Randomised Controlled Study |
| GAfREC | Governance Arrangement for NHS Research Ethics | REC | Research Ethics committee |
| IB | Investigator Brochure | SAR | Serious Adverse Reaction |
| HCP | Healthcare professional | SAE | Serious Adverse Event |

| | | | |
|---|---|---|---|
| ICECAP-O | Capability measure | SDV | Source Data Verification |
| ICF | Informed Consent Form | SOP | Standard Operating Procedure |
| ISRCTN | International Standard Randomised Controlled Studies Number | SSI | Site Specific Information |
| GHQ12 | General Health questionnaire: Short form | TAU | Treatment as usual |
| MDS-UPDRS | Movement Disorders Society-Unified Parkinson's Disease Rating Scale | UCL | University College London |

# 8 Reference

1 Tuijt R, Tan A, Armstrong M, *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. *Parkinson's Disease*. 2020;2020:e8857385. doi: 10.1155/2020/8857385