Title: **Care Where It Counts: Interdisciplinary Home Visits for PSP-Related Disorders**
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Rush University Medical Center

Title: Care Where It Counts: Interdisciplinary Home Visits for PSP-Related Disorders
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ABBREVIATIONS

CBS	Corticobasal syndrome
CSI-SF	Client Satisfaction Inventory – Short Form
CURE-PSP	CurePSP Foundation, supporting research and patient outreach for individuals with Progressive Supranuclear Palsy and related prime-of-life neurodegenerative disorders
DLB	Dementia with Lewy Bodies
ED	Emergency Department
EQ5D	Euro-Qol 5D – instrument for measuring quality of life
HRQOL	Health-Related Quality of Life
HY	Hoehn and Yahr Scale
HVP	Home Visit Program
MCSI	Multidimensional Caregiver Strain Index
MoCA	Montreal Cognitive Assessment
MSA	Multiple System Atrophy
PD	Parkinson's Disease
PDD	Parkinson's Disease Dementia
PDQ-39	Parkinson's Disease Questionnaire
PDQ-8	Parkinson's Disease Questionnaire – Short Form
PHI	Personal History Information
PI	Principal Investigator
PRD	Progressive Supranuclear Palsy and Related Disorders
PSP	Progressive Supranuclear Palsy
REDCap	Research Electronic Data Capture
UPDRS	Unified Parkinson's Disease Rating Scale

I. Project Rationale and Description

I.a. Purpose of the Study

The aim of this study is to test whether and to what degree an interdisciplinary home visit program will improve patient- and caregiver-reported outcomes and healthcare utilization when compared with usual care, and to identify unmet needs in this population. Evidence supports interdisciplinary and home-based models of care in other elderly populations, however no such models have been studied in people with PRD.[5] Improving access to comprehensive, specialized, in-home patient care and caregiver support offers the potential to minimize the downward spiral of morbidity and preventable healthcare utilization.[6,7]

Our objective is to expand the reach of comprehensive clinical care and research studies to homebound patients with PRD through an interdisciplinary home visit program bringing medical, nursing, and social work expertise directly to patients and caregivers. We hypothesize: 1) Home visit program subjects will show improved quality of life from the time of enrollment, to 1-year follow-up and will have better quality of life at 1 year compared with controls, as measured by change in EuroQoL-5 scores[8-10], respectively; 2) Program caregivers will show less deterioration in caregiver strain from enrollment to 1-year follow-up and will have lower strain at 1 year compared with controls, as measured by change in Multidimensional Caregiver Strain Index[11], respectively; and 3) Participants will express multiple unmet needs in several domains, including: education and resources for rare diagnoses, treatment of non-motor symptoms, palliative care, and end-of-life planning.[12,13]

I.b. Background

Progressive supranuclear palsy affects approximately 20,000 people in the United States. Progressive supranuclear palsy and related disorders (PRD) are debilitating, costly, and understudied conditions that significantly impacts patient quality of life and caregiver strain.[1,2] When patients with severe, neurodegenerative disease progress to the point that they can no longer access their usual care, their risk of hospitalization and institutionalization increases.[3,4] Unfortunately, when these same patients are hospitalized or institutionalized, they suffer from excess morbidity and mortality compared with individuals without movement disorders. There is a tremendous unmet need to foster continuity of care for the sickest patients with neurologic disease.

The study of individuals with PSP, and how a medical home visit model of care can benefit them, is an essential component of our movement disorders research. This study will include information collected during routine patient care (e.g., demographics, medication history, and standard motor assessments), detailed data on medication reconciliation and medication errors, periodic in-home clinical assessments, neuropsychological questionnaires, patient satisfaction with the home visit program and components, and resource utilization data. The assessments conducted in the research provide crucial data towards the understanding of how medical home visits can improve patient and caregiver quality of life, and reduce hospital and nursing facility admissions, versus controls, who do not receive medical home visits.

I.c. Study Design

The initial survey piloting of this study was already conducted at New York University (IRB approval date 3/1/2017, see uploaded IRB approval letter). Participants were recruited from the Fresco Institute at

NYU and contacted by the NYU study team to complete a cognitive interview in which the survey was administered and the participant answered the questions in real time, providing feedback on confusing, vague, or burdensome questions. We piloted the survey in 8 individuals, including both patients and caregivers.

In the home visit arm of the study, 25 individuals with PSP or PSP-related disorders living in Chicago and meeting Medicare "homebound" criteria will be recruited to the treatment (home visit) arm of the study. At the time of enrollment in the treatment (home visit) arm, clinical and demographic data about study subjects will be collected by study personnel, both directly from subjects and from retrospective medical chart review. Patients followed at the Rush Parkinson's Disease and Movement Disorders Program or followed elsewhere in Chicago who can provide medical records confirming their diagnosis of PRD, and who meet inclusion criteria for this study, will be offered the opportunity to participate by their treating neurologist at the time of or after their routine office visit (for individuals seen at Rush), or will be screened and contacted directly by the study team.

Subjects who are interested in participating will be given information about the study and the opportunity to ask questions about it in detail; those who opt to participate will be scheduled for an initial home visit (Visit 1), at which time, the verbal and written informed consent process will take place prior to completing any study activities.

Subjects who commence on study will receive four quarterly structured, interdisciplinary home visits over 12 months from a team comprised of a movement disorders neurologist, social worker and nurse. At Visit 1, the nurse, social worker, and a member of the research team will travel to the home. The neurologist will be present via telemedicine. The home visit team will travel with an iPad and, after obtaining informed consent, connect to the neurologist via HIPAA-secure videoconferencing and begin the protocol-driven clinical activities and assessments in Figure 1 in the uploaded protocol. The nurse will conduct and, with the neurologist, score the UPDRS Motor Examination, reconcile medications, and complete a standardized home safety assessment. The social worker will obtain demographics, and administer the Multidimensional Caregiver Strain Index (MCSI) to the caregiver and the EuroQoL-5D (EQ5D) to both the patient and caregiver, respectively. The social worker will conduct a needs assessment of the dyad, including a discussion of goals of care. The team will administer the same survey that the usual care subjects will complete as a structured interview, as individuals in the home visit arm are expected to have more difficulty with dexterity and potentially cognitive issues, limiting the feasibility of completing the online survey unassisted. The survey will cover demographics, disease history, comorbidities, healthcare utilization, and unmet needs of the patient and caregiver. The team will probe for further details on necessary services or resources, and will ask specifically about areas of need in: education, resources, non-motor symptoms, psychiatric and palliative care, spiritual and/or religious support, and end-of-life planning. The team will create and counsel the dyad on a care plan. Within the Rush electronic medical record, the neurologist will enter orders and send a comprehensive, template-based note to the patient's healthcare providers. Visits 2-4 will be conducted at 4-month intervals and are identical except the social worker may join by telemedicine, depending on availability, and the queries on unmet needs will only be repeated at Visit 4.

The visits may be performed where the subject is residing at the time of scheduled visit (which could include but not restricted to the subject's home, nursing facility, hospital, etc.). The duration of the visits will be approximately 2.5-3 hours for Visit 1 and 1.5-2 hours for Visits 2-4.

The study team will provide one scheduled follow-up call at about 4 weeks post-visit (though this call

may occur as early as 2 or as late as 8 weeks after each visit, depending on the individual subject's circumstances and the ability of the study team to reach the patient and/or caregiver by phone). Change in quality of life and caregiver strain will be assessed over one year. The home visit cohort will be compared to a "usual care" cohort as measured by individuals with PRD living in the community who complete the online survey annually for 2 years covering demographics, disease history, quality of life, and caregiver strain.

Sixty (60) control participants will be recruited from the Rush University Parkinson's Disease and Movement Disorders Program, NYU Parkinson's Disease and Movement Disorders Institute, CurePSP (via social media postings), and from the CurePSP network of support group participants via in-person presentations from study staff, printed fliers, and emails. Control participants will be invited to complete an online version of the survey, created using REDCap research electronic data capture technology (HIPAA-secure database) housed at NYU. Caregivers of controls, when available, will also be invited to complete the online survey.

Characteristics of the Research Population

II.a. Number of Subjects

Total Number of Subjects in Home Visit and Usual Care arms: 85

Number of Subjects in Home Visit Arm: 25 subjects with Progressive supranuclear palsy, multiple system atrophy, corticobasal syndrome, or atypical parkinsonism. Participation in the home visit arm neither requires nor prohibits participation in the survey pilot phase.

Number of Subjects in Usual Care Arm: 60 subjects with Progressive supranuclear palsy, multiple system atrophy, corticobasal syndrome, or non-idiopathic PD atypical parkinsonism. Participation in the usual care arm neither requires nor prohibits participation in the survey pilot phase.

This is an exploratory study; no power analysis was conducted. The number of home visit subjects was projected based on recruitment to pilot work at NYU and discussions with Rush colleagues regarding feasibility. The number of control subjects was based on discussions with CurePSP senior staff regarding the size of their support group and social media-connected networks.

II.b. Gender of Subjects

There will be no exclusion of subjects based on gender.

II.c. Age of Subjects

Subjects will be 40 years of age and older.

II.d. Racial and Ethnic Origin

There will be no exclusion of subjects based on racial or ethnic characteristics. Study demographics are expected to match those of the population from which it was drawn. However, subjects must be fluent in English to participate in the Home Visit Program due to the general lack of appropriately translated

neurological and neuropsychological assessments and appropriate normative comparison samples. These factors are critical for accurate administration, scoring, and interpretation of neurological and neuropsychological test data.

II.e. Inclusion Criteria for All Subjects:

1. Each subject must be 40 years of age or older. A subject may be of either gender, any race/ethnicity.
2. Subjects will be those diagnosed with progressive supranuclear palsy, multiple system atrophy, corticobasal syndrome , Dementia with Lewy Bodies (DLB), or atypical parkinsonism without mention of idiopathic Parkinson's disease.
3. English speaking.
    a. **Additional Inclusion Criteria For Home Visit Arm:**
        i. Each subject must *either* 1) be willing and able to provide written, informed consent for the study, and for whom capacity to consent will be assessed using the "Additional Inclusion Criteria for Home Visit Arm" document, or 2) if unable to provide informed consent due to lack of capacity, a caregiver is able to provide informed consent *and* the subject provides assent to participation.
        ii. Subjects must be homebound according to the Medicare definition: "Leaving your home isn't recommended because of your condition; your condition keeps you from leaving home without help (such as using a wheelchair or walker, needing special transportation, or getting help from another person); leaving home takes a considerable and taxing effort." (http://www.medicare.gov/pubs/pdf/10969.pdf)
        iii. Subjects reside in Chicago at the time of Visit 1.
        iv. The Subject must reside independently at the time of Visit 1.
        v. Subjects have one or more of the following criteria:
            - Fluctuation
            - Multi-morbidity
            - Mismanages medication
            - Cognitive impairment
            - Symptoms of depression and/or anxiety
            - High risk for re-hospitalization
            - High risk for nursing facility admission
            - Suspected elder abuse
            - Recent history of increased falls in home
            - Caregiver burnout suspected
        vi. Ability to participate in the research study as deemed by the Principal Investigator.

    b. **Additional Inclusion Criteria for Usual Care Arm:**
        a. Independent access to an internet-connected computer in order to complete online survey
        b. Valid email address

c. Each subject must review and acknowledge their ability to provide informed consent for the study via the first screen of the online survey.

II.f. Exclusion Criteria for All Subjects

1. Diagnosis of idiopathic Parkinson's Disease
2. Diagnosis of another neurodegenerative disease (e.g., amyotrophic lateral sclerosis, frontotemporal dementia)
3. Subjects with active psychosis or exhibiting symptoms of a severe psychiatric disorder.

II.g. Vulnerable Subjects – This study will not include children, prisoners, and homeless persons. The consent form will state that participation in our study will **not** affect their clinical care. These subjects will be evaluated by clinicians (neurologist—either movement disorders attending or fellow; social worker; nurse) trained in evaluating and treating subjects with cognitive impairments. Cognition is impacted by Progressive Supranuclear Palsy, Corticobasal Degeneration, and Dementia with Lewy Bodies, with increasing prevalence of cognitive impairment over time, and thus the homebound, advanced PRD population suffers from a high burden of cognitive decline. Therefore, it is important to include patients with and without cognitive impairment to understand possible treatment and care options for this population and for the results of our study to be generalizable to the broader advanced PD population.

III. Methods and Procedures

Study Visits

Home Visit Subjects: The study team will screen clinical records and review physician-referred patients. They will contact potential patients or patient-caregiver dyads to review the study objectives, eligibility criteria, and scheduling.

At Visit 1, the nurse, social worker, and a member of the research team will travel to the home. The neurologist may be present in person or via telemedicine. If the neurologist is present via telemedicine, the home visit team will travel with an iPad and, after obtaining informed consent, connect to the neurologist via HIPAA-secure videoconferencing and begin the protocol-driven clinical activities and assessments in Figure 1. The nurse will conduct and, with the neurologist, score the UPDRS Motor Examination, reconcile medications, and complete a standardized home safety assessment. The social worker will obtain demographics, and administer the Multidimensional Caregiver Strain Index (MCSI) to the caregiver and the EuroQoL-5D (EQ5D) to both the patient and caregiver, respectively. The social worker will conduct a needs assessment of the dyad, including a discussion of goals of care. The team will administer the same survey that the usual care subjects will complete as a structured interview, as individuals in the home visit arm are expected to have more difficulty with dexterity and potentially cognitive issues, limiting the feasibility of completing the online survey unassisted. The survey will cover demographics, disease history, comorbidities, healthcare utilization, and unmet needs of the patient and caregiver. The team will probe for further details on necessary services or resources, and will ask specifically about areas of need in: education, resources, non-motor symptoms, psychiatric and palliative care, spiritual and/or religious support, and end-of-life planning. The team will create and counsel the dyad on a care plan. Within the Rush electronic medical record, the neurologist will enter

orders and send a comprehensive, template-based note to the patient's healthcare providers.

Visits 2-4 will be conducted at 4-month intervals and are identical except the social worker may also join either in person or by telemedicine, depending on availability, and the queries on unmet needs will only be repeated at Visit 4. The visits may be performed where the subject is residing at the time of scheduled visit (which could include but not restricted to the subject's home, nursing facility, hospital, etc.). The duration of the visits will be approximately 1.5-2 hours.

If, in the course of any of the home visits, or in the course of any post-visit follow-up either initiated by the subject, caregiver (if applicable), or the study team, any member of the study team suspects adult abuse or that the subject is of imminent danger to themselves or others, that study team member will discuss those concerns with the study nurse, physician, and social worker either immediately at the time the concern arises (in the case of concerns arising during a home visit, as detailed below), or as soon as that discussion is feasible, in the case of a follow-up phone call or other contact.

If there is an immediate concern during a home visit and the study team member feels uncomfortable or unsafe raising the concern in front of the subject and/or caregiver, all team members will be trained in the following "time-out" procedure: Any team member may use the phrase, **"I think that the team needs to step outside for a moment"**, at which time all team members will acknowledge this and safely exit the subject's home either into a hallway (for apartments or condominiums) or outdoors (for independent dwellings). If the team is connected to the physician by telemedicine at that time, the team will bring the iPad with them. If the team is not connected at that time, they will connect with the physician before proceeding with the discussion. The concerned team member will describe their concern, solicit additional input from other team members, and if *any one* of the mandated reporters—nurse, social worker, or physician—agree that there is sufficient evidence for concern, the team will devise an intervention strategy. If there is a concern for adult abuse—including physical abuse, sexual abuse, emotional abuse, confinement, passive neglect, willful deprivation, or financial exploitation—the team social worker will be responsible for contacting Adult Protective Services (APS) to report the suspected abuse, neglect, or exploitation at 1-866-800-1409, and for notifying the subject and/or caregiver of this report. If the team feels that disclosing this intent to report in the presence of the subject and/or caregiver would pose additional risk to the subject and/or study team, the team will conscientiously express their concerns to the subject and/or caregiver upon re-entering the home, but may defer specific discussion of the impending APS report for safety purposes. The team social worker will be responsible for contacting APS within 1 business day of the visit, documenting this in the electronic medical record, and routing this documentation to the remainder of the study team. Similarly, the social worker will be responsible for following up on and notifying the team of the outcome of the APS referrals in a timely fashion.

In the event that a subject or caregiver is felt to be an imminent danger to themselves, the team will use the procedure above *except* that the research assistant will remain with the subject and/or caregiver for safety purposes while the remainder of the team convenes outside of the home to discuss the concern. If any one of the nurse, social worker, or physician agree that there is sufficient concern for suicide risk, the nurse will contact 911, the social worker (and physician via telemedicine) will rejoin the subject/caregiver and research assistant, and all will remain with the individual(s) until emergency medical personnel arrive. The team will let the subject/caregiver know about their concerns and the 911 call, and will provide supportive counseling while awaiting the arrival of emergency medical personnel and transport of the concerning individual to the nearest appropriate medical facility.

Usual care/controls: Control subjects, and caregivers if available, will each complete an online survey querying the same demographic, diagnostic, disease history, needs, resource utilization questions, and the EQ5D. If the control subject indicates that she or he has an available and willing caregiver, the subject will be prompted to have their caregiver complete the caregiver portion of the survey once the subject has completed his portion. Control subjects will be contacted 12 months following the initial survey to complete a follow-up survey. Control participants and CurePSP support group leaders will be reminded to complete the survey; the study team will then email all control subjects with incomplete surveys one week after the initial email and with up to 3 email reminders to maximize response rate.

Assessments: Home visit subjects who agree to be part of the study and sign the Informed Consent Form will be asked to complete a series of neurological and neuropsychological assessments to assess their current neurological status, intellectual functioning, memory, and mood. There is no known risk associated with participation in these assessments, and they are a part of routine clinical care for these conditions. These tests can be cognitively demanding but are typically experienced as interesting to subjects. Administration of these assessments should take approximately two hours. All study assessments are specified in Appendix A, in the Schedule of Events table. All or some of the following neurological assessments and self-report measures may be administered but are not limited to:

- *Unified Parkinson's Disease Rating Scale (UPDRS):* A rating scale used to follow the longitudinal course of Parkinson's disease, applicable to PRD

- *Hoehn and Yahr Scale (HY):* A system used for describing how Parkinson's symptoms progress and the relative level of disability. There are five stages: Stage 0 – No signs of disease; Stage 1 – Unilateral disease; Stage 1.5 – Unilateral plus axial involvement; Stage 2 – Bilateral disease, without impairment of balance; Stage 2.5 – Mild bilateral disease with recovery on pull test; Stage 3 – Mild to moderate bilateral disease; some postural instability; physically independent; Stage 4 – Severe disability; still able to walk or stand unassisted; Stage 5 – Wheelchair bound or bedridden unless aided.

- *Montreal Cognitive Assessment (MoCA) and abbreviated versions of the MoCA:* a brief 30-point questionnaire test that is used to screen for cognitive impairment and has been extensively validated in PD; also used to estimate the severity of cognitive impairment at a specific time and to follow the course of cognitive changes in an individual over time, thus making it an effective way to document an individual's response to treatment. Any score greater than or equal to 24 points (out of 30) is effectively normal (intact). The raw score may also need to be corrected for educational attainment (additional 1 point added to total score if $\leq$12 years of education).

- *Euro-Qol 5D (EQ5D):* a brief, extensively validated, 6-item instrument measuring five specific domains of health-related quality of life (mobility, self-care, activities of daily living, anxiety/depression, pain/discomfort) and overall well-being. This instrument has been validated for use as a self-administered survey in paper and online via the REDCap software package, as well as having been validated for use with the assistance of an interviewer.

- *Multidimensional Caregiver Strain Index (MCSI):* A validated 18-item tool measuring 6 dimensions of subjective response to stressors. Subscales include physical strain, social constraints, financial strain, time constraints, interpersonal strain, and elder demanding/manipulative. Respondents are asked about the frequency with which items apply, ranging from “never” to “all of the time” on a 5 point scale.

- *Client Satisfaction Inventory – Short Form (CSI-SF):* A validated, 9-item instrument developed within the field of social work to assess client satisfaction with multidisciplinary programs. Each item consists of a statement in the first-person, and subjects respond on a 7-point Likert scale to indicate their satisfaction with usual care at baseline, and with the HVP at Visit 4. One copy each will be provided to the subject and the caregiver (if present).

III.b. Data Analysis and Data Monitoring

Oversight of the Data: CARE-PSP will be maintained by the Principal Investigator. The Principal Investigator will review study procedures annually and report any concerns in the IRB continuation application. This is a Level I, Low, Minimal Risk study; therefore, there is minimal risk of unanticipated problems with the exception of breaches in confidentiality. The data for the study will be entered into a secured database using an electronic data capture program such Research Electronic Data Capture (REDCap).[15] The database will be stored on a secure password-protected server and not on individual desktop computers. The code sheet will be password protected and the password will be updated annually. Breaches of confidentiality will be reported to the IRB immediately with the "Reportable Event/Unanticipated Problem Form."

The PI, co-investigators, and/or study staff will review all data collection forms on an ongoing basis for data completeness and accuracy as well as protocol compliance. The data will be reviewed on a quarterly basis:

- Subject accrual (including compliance with enrollment criteria)
- Status of all enrolled subjects
- Adherence data regarding study visits and procedures

Safety data (AEs and SAEs) will be reported to the Principal Investigator and reviewed per occurrence and in accordance with the IRB's regulations. Any significant findings (i.e. protocol deviations) will be reported to the IRB in accordance with requirements and will be documented accordingly.

III.c. Data Storage and Confidentiality

All subjects will be assigned unique ID numbers. All research data files will be stored at the Rush University Parkinson's Disease and Movement Disorders Program in secured file cabinets, including case report forms for home visits, informed consent forms and informed consent documentation checklists. Data will be entered into a secured database using an electronic data capture program such Research Electronic Data Capture (REDCap).[15] The database will be stored on a secure password-protected server and not on individual desktop computers. The code sheet will be password protected and the password will be updated annually. Hard copies of case report forms and informed consent documentation checklists will be labeled with the study ID only and maintained in individual files by study ID number. Signed informed consent forms, containing subject names, will be stored separately in the regulatory binder, which will be stored in a locked file cabinet in the PI's office.

Only the PI, Co-investigators and research staff will have access to the database and hard copies of study documents. During the consent process, the potential participant will be informed that aspects of their

PHI will be shared with collaborating researchers at Rush, including Dr. Deborah Hall; however, they will have an opportunity to decline having their PHI shared and still participate. Data will be stored in a format suitable for research inquiries by the PI and Co-Investigators, who might make use of the data in a retrospective manner for other Rush-based research studies. The data collected from this study is restricted to access by the PI and direct study collaborators at Rush, including mentors Dr. Deborah Hall. No collaborator will be allowed to share the data outside the study team without the PI's written approval. Collaborators interested in using the data outside of this study will be required to provide a written request to the PI noting the specific data fields of interest, a description of how the data will be used and who will have access/use the data. The PI reserves the right to grant/deny approval to any collaborator prior to the release of any study data. If a particular researcher/collaborator has an interest in a study population, then the PI will review the database to identify eligible subjects that meet the study inclusion criterion and the potential participant(s) will then be contacted by a member of this study team whom the subject has already met to see if they are interested in participating in the particular study. If a participant is interested, he or she will be referred to that Rush study team and will be scheduled for a separate consent procedure with the individual Rush researcher for that particular study and at that point the participant can choose whether to participate or not in that particular study. The results of the CarePSP study may be published in a book, journal, and other media or used for teaching purposes. However, all published data will be made anonymous.

IV. Risk/Benefit Assessment

IV.a. Risk

There are no known risks from participating in neurological or neuropsychological tests. Subjects may experience mild boredom or cognitive fatigue; however, most individuals with like symptoms find the tests interesting and are able to tolerate up to two-hour duration of testing well. There is, however, a risk that the study team may, in the course of any given visit to the home or contact with the subject and/or caregiver following a visit, detect evidence concerning for adult abuse or suicidal ideation. In these instances, the nurse, physician, and social worker are mandated reporters of these conditions and may contact either Adult Protective Services or activate Emergency Medical Services (911), as appropriate, to ensure the safety of the subject. The subject will be notified if such a report is filed.

IV.b. Potential Benefit to Subjects

The potential benefits to home visit subjects specifically are as follows: (1) the possible diagnosis of unsuspected depression, anxiety, or cognitive disorders, for which the subjects would then be able to receive prompt treatment (through referrals to physicians in the appropriate neurological or psychiatric clinic at NYU or comparable clinic(s) of their choice). The potential benefits to all subjects are as follows: (1) the satisfaction of having contributed to scientific knowledge about progressive supranuclear palsy and related disorders that may help to increase the quality of life of themselves and other subjects with movement disorders. The potential impact of this and future studies is a model of care to improve quality of life and caregiver strain for thousands of individuals with PRD. The potential benefit to society includes: (1) increasing the independence, quality of life, and productivity of patients with PRD, (2) extending medical treatment, psychosocial support, and health education into the home, (3) enhancing patient safety, (4) increasing patient access to care, (5) reducing hospital readmissions and admissions to long-term care facilities, (6) reducing caregiver strain, and (7) decreasing healthcare utilization and

costs. In our opinion, the individual and societal benefits clearly outweigh the minimal risks of participation in this study.

V. Subject Identification, Recruitment, and Consent/Assent

V.a. Method of Subject Identification and Recruitment

Patients who are under care of the PI or any referring movement disorders provider at the Rush University Parkinson's Disease and Movement Disorders Program who meet the inclusion criteria for this study, will be offered further information about the study by their treating neurologist at the time of or after their routine office visit, directed to an available study team member for additional information, or will be screened and contacted directly by the study team. Subjects who are interested in participating will be given further information about the study. Subjects living within the catchment area but seen at other institutions may receive information about the study through their involvement with local CurePSP support groups. Support groups will provide the IRB-approved recruitment fliers to their participants, with contact information for the study team. Upon contacting the study team, the team member will review the eligibility criteria with the potential participant; if met, the team member will proceed with scheduling the first study visit, at which time the consent process will take place as described below.

V.b. Process of Consent

Home visit subjects: Subjects will be asked to carefully read the respective IRB-approved Informed Consent Form. The trained research study team member, will obtain consent in a private, distraction-free area in the patient's home. The person obtaining written informed consent from the subject will assess capacity to participate in the research study. It is not practicable to have an individual independent of the study team perform the capacity assessment or obtain informed consent because both are done in the potential subject's home, and both space and funding limit the number of individuals who can practically attend a visit.

Subjects who consent to be contacted about future studies will be notified of potential studies that they are eligible for as studies are available for recruitment. Their consent to participate in the CarePSP study does not apply to other studies. As such, subjects will have to go through the respective consent processes separately. Subjects have the right to refuse participation in any study without consequence to their participation in the registry or their routine patient care. Subjects will be informed about their right to request not to be contacted for specific periods of time or to discontinue active participation in the program, although their data will continue to be stored for future use.

Usual care subjects: We have incorporated the components of the informed consent document into the first page of the online survey. Potential subjects must read through the informed consent language on the first page and click a button agreeing to continue. On the next page of the survey, we have incorporated capacity assessment questions to ensure understanding of the consent process. Following correct completion of these questions, the potential subjects are then directed to the actual survey questions.

V.c. Subject Capacity

Capacity to consent will be assessed by the designated trained research staff member and/or the PI. Throughout the consent process, the study staff member will assess the participant's comprehension by asking the participant to verbally summarize key elements of the consent form particularly the sections of the consent form that explains that they are being asked whether they agree to be contacted for other studies, as well as aspects of the consent form that explain the inclusion of PHI in the database, how their confidentiality will be protected, and how their data will be stored for future use.

Subject's capacity is not expected to fluctuate significantly, however cognitive fluctuations can be seen in some PRD patients with dementia, such that an individual varies from having capacity to not having capacity, and back again within the span of hours. If in the course of the routine clinical activities of the visit, the clinical or study team members are concerned about capacity, the study team will reassess capacity by asking the original capacity assessment questions. If the subject no longer has capacity, then surrogate consent would be required to proceed with the study visit; if no surrogate, the subject would be withdrawn from the study but would not be dropped from the clinical program providing their care. Subjects who regain capacity at a subsequent clinical visit would need to provide self-consent again. Subjects who refuse capacity assessment cannot be in the study.

During the consent process, subjects will have the opportunity to indicate whether they wish to be contacted for participation in future studies conducted by researchers at Rush and their collaborators or only be part of CarePSP. Subjects who agree to participate in the program will also have an opportunity to authorize having their Personal History Information (PHI) shared with our collaborators. PHI data will **NOT** be shared unless written authorization is obtained from the subject.

Home visit subjects will be given a copy of the signed IRB approved Informed Consent Form for their future reference. Signed consent forms will be stored in a locked cabinet in the PI's office at Rush, separate from the study data.

Subjects who are unable to provide meaningful written, informed consent due to cognitive deficits will be asked whether their caregiver may provide informed consent. The caregiver (i.e. next of kin, health care proxy, court appointed LAR, etc.) will then be asked to give consent for participation in the study as above, with assessment of capacity as above. If the subject does not have a caregiver that is able to provide consent for the subject, the subject will not be eligible to enroll in the study. If subject does have a caregiver, and the caregiver has capacity to consent and provides informed consent, the subject will be asked for assent to participate, as stipulated in the Alzheimer's Association's recommendations for research consent for cognitively impaired adults.[14] If the subject provides assent *or* does not dissent, then the subject may be enrolled.

V.d. Debriefing Procedures

Subjects will not be debriefed about the aims and study hypotheses following administration of all study procedures due to the nature of the study and the data collected.

V.e. Documentation of Consent

A Consent Process Documentation Form will be included in the home visit subjects' research chart that will document the informed consent process that took place. For usual care subjects, their online survey data will contain an indicator that they have read and agreed to the consent language.

V.f. Costs to the Subject

Subjects will not receive any inducements before, or rewards or compensation (i.e. cash, taxi fares, medical care, gifts, etc.) after the study. There will be no cost to subjects associated with participation in this study.

VI. References

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Appendix A: Schedule of Events

Figure 1. Diagram of Study Visit Activities and Assessments

Activities: OS = online survey; IP = in-person; TH= telehealth

INTERVENTION ACTIVITIES AND RELATED ASSESSMENTS		**Visit**			
		1	**2**	**3**	**4**
Usual Care Arm	Online survey (OS; demographics, disease history, resource utilization, unmet needs)	OS			OS
Home Visit Arm	**Screening Telephone Call** Screen for eligibility and schedule visit	TH			
	Visit – Clinical Activities RN: Informed consent documentation	IP			
	RN: UPDRS I-II, vitals, medication reconciliation	IP	IP	IP	IP
	RN: Home safety assessment	IP			
	MD: Medical history, UPDRS III-IV	TH	TH	TH	TH
	SW: Psychosocial assessment of dyad	IP	TH	TH	TH
	MD: Counseling, summarize plan of care	TH	TH	TH	TH
	Visit—Assessments Dyad demographics, disease history	IP			
	Resource utilization questionnaire, MCSI	IP	IP	IP	IP
	UPDRS (I, II, III, IV subtotals), HY, EQ5D	IP	IP	IP	IP
	Unmet need assessment (identical to OS), short MoCA	IP			IP
	CSI-SF				IP
	Post-Visit Follow-Up MD, RN, SW document comprehensive visit	TH	TH	TH	TH
	~4week follow-up calls (RN or SW)	TH	TH	TH	TH

Visit 4: 365 +/- 60 days after Visit 1.
OS: Online survey; RN: Registered nurse; SW: Social worker; MD: Neurologist
UPDRS: Unified PD Rating Scale; MCSI: Multidimensional Caregiver Strain Index; HY: Hoehn & Yahr; EQ5D: Euro-Qol 5-D quality of life scale. MoCA: Montreal Cognitive Assessment; CSI-SF: Client Satisfaction Inventory, Short Form