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Title of Study: IN-HOME-PD: A Novel Model of Care in Advanced Parkinson's Disease

Protocol Number: 17080209

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Subject Information Sheet and Consent Form **HVP-Caregiver Subjects**

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand.

You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

Why are you being invited to participate in this study?

You are being asked to take part in this study because you are an informal caregiver to a patient at the Rush Parkinson's Disease and Movement Disorders Program who has been diagnosed with Parkinson's Disease (PD) or a related disorder and who is eligible to participate in the Home Visit Program (HVP) research study. The information (data) collected from the study participants will be compared to data available in the National Parkinson's Foundation's Parkinson's Outcome Project. The data will be matched according to age, gender, and disease severity. Your involvement in the study will contribute to scientific knowledge about whether home visits with individuals with PD can improve patient quality of life, decrease the level of caregiver strain, and help reduce the number of emergency room and hospital visits, and admissions to long-term care institutions.

What is the purpose of this study?

Advanced PD is a debilitating, costly, and understudied condition. Improving access to comprehensive, specialized, in-home patient care and caregiver support offers the potential to improve patient quality of life of PD symptoms. The purpose of this study is to test whether and to what degree an interdisciplinary home visit program, with and without peer mentoring for caregivers, will improve patient- and caregiver-reported outcomes over the course of one year and reduce healthcare costs when compared with usual care in advanced PD.

How many study subjects are expected to take part in the study?

We estimate 65 people will participate in the home visit patient arm, plus a caregiver for each home visit patient (65 caregivers), plus 40 caregiver peer mentors for a total of 170 people participating. The three study arms include home visit patient subjects, home visit caregiver subjects, and caregiver peer mentors.

What will you be asked to do?

If you agree to participate in the study, you will be asked to participate in four home visits, which will involve in-home clinical assessments and completion of some questionnaires. After the first home visit, you will then be matched with a “peer mentor”: this individual is a prior caregiver to someone with PD who is interested in sharing their knowledge, experience, and time to help improve the lives of current caregivers, like you. For a period of 4 months between home visits 2 and 3, you will be asked to meet with your peer mentor, who will be trained to serve as a resource and listening ear, in addition to the medical team. We will measure your satisfaction with the home visit program alone, as well as the mentoring program.

Home Visit 1:

This visit will be about 3 hours in length. This visit will begin with the completion of this consent form, followed by collection of basic information about you and your loved one with PD, such as age and education, and brief medical and social history. Next, a nurse will measure your loved one’s vital signs, complete a home safety assessment, and medication reconciliation, in which s/he verifies that our records of your loved one’s medication regimen are correct and consistent. A neurologist will be present by telemedicine (videoconferencing) and will perform a neurological examination on your loved one, much like the examination performed at office visits to your neurologist. The team will also complete a brief exam which assesses your memory and that of your loved one.

Then, a social worker and/or a nurse will administer various questionnaires about your current function and concerns, and those of your loved one. The social worker will ask you questions as part of a psychosocial assessment. To conclude, you will have an opportunity to discuss any concerns you have about your health or care which have not yet been addressed. The team may suggest referrals which may support or improve your care.

Visits 2 and 3:

These follow up visits will be about 2 hours in length each. These visits will include the same components as the first visit, with the addition of caregiver mentorship visits or meetings, and a satisfaction survey, but without the repetition of consent or collection of basic information completed at your first visit. The second and third visit will occur approximately four months apart, and sometime between the first and fourth visit; you will have an opportunity to schedule these visits with the HVP research team at your convenience.

During the follow-up visits, you will be asked to complete some questionnaires, some of which will be self-administered and some of which will be administered by a study staff member. For the second, third, and fourth visits, the social worker may be present in person or by videoconferencing. This means that the study team will visit you at your home and bring an iPad or other technology that allows you to see and talk with the doctor and ask any questions you might have.

Visit 4:

The fourth visit will be scheduled approximately 1 year (+/- 60 days) from your initial study visit. You will again be asked to complete some of the same assessments that you completed during the first visit, and a new assessment about your satisfaction with the HVP.

Peer Mentoring:

Once you have completed the second home visit, you will be contacted by a member of the study team and you will be given the name and contact information for your mentor. The study team will help coordinate the first mentoring visit, which can take place in-person at a location chosen with your mentor, or by phone, or by videoconferencing on the iPad that you are given by the study team.

During the first meeting, your mentor will introduce himself or herself, set expectations for the mentoring relationship, and learn about you, your loved one, and your unique situation. You will agree upon a date, time, and method for the next meeting. You will complete a study diary entry to document the date of meeting, type of meeting (in-person, phone call, videoconference), length of meeting, and topics discussed.

You will then meet with your mentor each week for at least 30 minutes for a total of 16 weeks, either in-person, by phone, or by videoconference. Your mentor may raise certain topics for discussion, or bring up resources that might be helpful to you, and you are encouraged to raise topics or concerns that are important to you and your loved one. After each meeting, you will complete a brief study diary entry.

A member of the study team will check in with you and your mentee individually by phone or email at weeks 2, 4, 8, 12, and 16 of the 16-week mentoring program to make sure the mentoring visits and relationship are going well, and to assist with any concerns.

During the final two weeks of visits (weeks 15 and 16), you will focus on ending the mentoring relationship, and after the last visit, the study-provided iPad will be collected from you by a member of the study team. You may continue to talk with your mentor beyond the 16 weeks if you both choose to continue the relationship, but you will not be expected to do so, nor will you need to maintain a study diary if you do. After you finish the 16 weeks of mentoring, you will complete several brief surveys on your experience.

How long will you be in the study?

You will be in the study for approximately one year, starting with an initial 3 hour home visit. Three follow-up home visits will take place after the initial visit, occurring approximately every three to four months. You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you or to the study team, you are unable to participate in the study as directed, or the study is canceled.

What are the possible risks of the study?

There are no known risks from participating in neuropsychological tests. You may experience mild boredom or cognitive fatigue; however, most individuals find the tests interesting and are able to tolerate 2-3 hours of testing well. You can skip any questions that make you uncomfortable or that may cause you emotional distress.

You may feel uncomfortable sharing information about yourself or your loved one with a person who you do not know, however the mentors are all 1) experienced past caregivers who have been in similar situations caring for their own loved ones with PD; 2) trained by the study team to listen actively, serve as good mentors and resources, and respect confidentiality.

Are there benefits to taking part in the study?

The potential benefits to you are as follows: Time and travel costs saved by having the team of clinical specialists come directly to your home rather than you needing to arrange for transportation to an outpatient clinic; the possible improvement of your loved one's motor and nonmotor symptoms, yielding possible relief of any physical and emotional caregiving burden you may have; increased independence or respite care due to recognition of the need for and referrals to respite care, home health agencies, meal delivery services, and other community services; increased confidence in your ability to reach certain goals due to education by HVP team and peer mentor on PD caregiver resources; decreased depression, anxiety, and caregiver strain due to continuity of care, improvement of HVP-patient subject's physical and neuropsychiatric condition, and positive relationship with and emotional support from a caregiver peer mentor. Additionally, you will have full access to a study-provided iPad for the 16-week duration of the peer mentoring intervention, during which time you may use the device for other purposes such as reading patient education online, journaling, gaming, using mindfulness or relaxation applications, or using videoconferencing applications for communication with friends and family.

The potential benefit to society includes: (1) increasing the independence, quality of life, and productivity of patients with PD and other movement disorders, (2) extending treatment and support into the home, (3) enhancing safety, (4) increasing access to care, (5) reducing hospitalizations and nursing home placements, (6) reducing the strain on caregivers, and (7) decreasing the costs of unnecessary or dangerous healthcare.

What other options are there?

Instead of participating in this study, you may choose another form of treatment such as:

- You may choose to continue to seek care for your loved one with PD at the Rush Parkinson's Disease and Movement Disorders Program or elsewhere regardless of whether or not you choose to participate in the study.
- As an alternative to entering the study, you may choose to seek care for your loved one from home care service agencies. You are free to discuss alternatives to entering this study with your personal physician.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. We are asking for your permission to use and to disclose your health information in connection with this study. You have the right not to give us this permission, in which case you will not be able to participate in this study. If you participate, you will be assigned a unique identification number. Your name and other identifying information will only be associated with your identification number on a code sheet that will be password-protected

and stored separately from all other study documents. The data for the study will be entered into a secured, electronic database that is password protected. Only the study team will have access to the database, which is protected by the Rush University electronic security systems and firewall. All paper copies of documents related to the study will be reviewed for any identifying information, and should such information be detected, it will be removed. All paper copies of documents will contain only your unique identification number.

This study is sponsored by the National Institute for Neurological Diseases and Stroke (NINDS), a branch of the National Institutes of Health (NIH). The NIH may require access to your files as they pertain to this research study as part of routine monitoring or in the event of an audit.

If you withdraw from this study, the data already collected may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Your identity will not be revealed on any report, publication, or at scientific meetings. In order to conduct the study, the study doctor, Dr. Jori Fleisher, will use and share personal health information about you. This includes information gathered during study visits in the form of interview questions, surveys, and questionnaires. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

A description of this study will be available on <http://www.CLINICALTRIALS.gov>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What are the costs of your participation in this study?

There will be no cost to you associated with participation in this study. The home visits, educational information, follow-up phone calls, and peer mentoring are provided free of charge by the study. However, in the course of this study, we may refer you or your loved one to a medical, therapeutic, and/or social service that we believe would benefit your care. It is your choice whether or not to obtain these services. The cost of these services will not be covered by study. You and/or your health insurance may be billed for the costs of these services as part of usual medical care. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility. You may choose to decline any referrals at any time.

What financial disclosures apply to this study?

Rush University Medical Center is being paid by the National Institutes of Health (NIH) to conduct this research. A portion of this money may go to the study doctor to compensate for

other institutional research related costs.

Will you be compensated or paid?

You will not receive any incentives, rewards or compensation for being in this study.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage. If you have any medical problems during the study, please contact the study doctor. He or she will explain your treatment options to you and/or help you find a place to get treatment.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study. NIH has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you notify the study doctor as soon as possible. Your loved one will be provided with an Aware in Care kit as part of this study, which you should bring with you to the emergency room or hospital any time he or she needs to go. The kit contains a wallet card with his or her identifying information and the contact information for the study doctor.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Dr. Jori Fleisher, (312) 563-2900. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

Name of Subject

Signature of Subject

Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of Individual Obtaining Consent

Date of Signature

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

SIGNATURE OF THE PRINCIPAL INVESTIGATOR

I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator

Date of Signature

☐ Check here if Principal Investigator obtained consent and a separate signature is not required.