Investigator: Jori Fleisher, MD MSCE

Contact Information: Rush Parkinson's Disease and Movement Disorders Program
Rush University Medical Center
1725 W. Harrison Street, #755
Chicago, Illinois 60612
(312) 563-2900

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

Protocol Number: 17080209

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RUSH

Subject Information Sheet and Consent Form
Caregiver Peer Mentors

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 asked to participate in this study because you are or have previously been an unpaid caregiver to a patient who has been diagnosed with Parkinson's Disease (PD) or a related disorder. We are recruiting and training experienced caregivers like you to serve as "caregiver peer mentors" to less-experienced caregivers. We think that experienced caregivers have a great deal of experience and knowledge about the 24-hour job of caring for someone with PD. Often, when one is no longer actively caregiving, it might feel that your experience is not being put to use. Also, when one is no longer actively caregiving, one might feel lonely or isolated.

We believe that by pairing an experienced caregiver like you with another less-experienced caregiver "mentee", and by training you to be a "mentor", you may help your mentee cope with the demands of caregiving by sharing your knowledge and experience. This may help both the mentee and their loved one, and it may also offer benefits to you, such as validation of your experience as a caregiver. The information (data) collected from study participants will be compared to data from National Parkinson Foundation's Parkinson's Outcome Project, a national project which monitors care over time of individuals with PD and their caregivers.

What is the purpose of this study?

The purpose of this study is to evaluate what degree a home visit program consisting of in-home visits with clinical specialists from multiple healthcare disciplines, with the addition of caregiver peer mentoring, will improve outcomes for patients with Parkinson's Disease (PD) and their caregivers over the course of one year. The potential impact of this and future studies is a model of care to improve quality of life, caregiver strain, caregiver depression and anxiety, and the usage of available healthcare resources for thousands of individuals with PD. Your involvement in the study will contribute to scientific knowledge about whether peer mentoring for caregivers of individuals with PD can improve caregiver strain, depression, anxiety, and self-efficacy. Your involvement will also identify areas of unmet need, which may guide healthcare providers and researchers towards better treatment in the future.

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

We estimate 65 people will participate as home visit patients (65 patients), plus a caregiver for each home visit patient (65 caregivers), plus 40 caregiver peer mentors for a total of 170 subjects.

What will you be asked to do?

Mentor Training:

This will be held at Rush and will last approximately five hours. If you live within 60 miles of Rush you will be given a roundtrip subway pass or a parking pass to compensate you for travel. If you live more than 60 miles from Rush, you will be reimbursed up to $585 to cover the cost of a flight, ground transportation to/from the airport, and a one-night hotel stay in order for you to attend the training session. You will meet with the Principal Investigator and the research study team to learn about the study. This will begin with the completion of this consent form, followed by study assessments and training on the following topics:

1. Baseline assessments about prior caregiving experience, emotional state, and self-efficacy
2. Active listening and mentoring
3. Advanced Parkinson's Disease and palliative care issues
4. Nursing and caregiving issues
5. Curriculum of concerns and resources, review of study handbook
6. Video conferencing training
7. Study diary training
8. Brief interviews with the study team to confirm willingness and ability to participate.

The initial study assessments will collect basic information such as age, education, caregiving experience, and self-efficacy. You will have ample time for breaks and refreshments. You will be encouraged to ask questions of the study team throughout training and anytime thereafter, and you will be given contact information for the study team.

Weekly Mentoring Visits:

Once you have completed the mentorship training, you will be contacted by a member of the study team within 1-4 months and you will be given the name and contact information for your first assigned mentee. You will be paired with one or two mentees during your participation in the study. Depending on study needs and your availability, you may be paired with these mentees at any time during your participation, with up to a 4 month period of time between being paired with your first and second mentee. The study team will help coordinate the first mentoring visit, which can take place in-person at a location chosen with your mentee, or by phone, or by videoconferencing.

During the first meeting, you will use the study handbook and skills you learned at mentor training to introduce yourself, set expectations for the mentoring relationship, and learn about your mentee, his or her loved one, and their 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, and videoconference), length of meeting, and topics discussed.

You will meet with your mentee each week for at least 30 minutes for a total of 16 weeks, either in-person, by phone, or by videoconference, and your discussion will be guided by the curriculum in the study handbook as well as your own experience. After each meeting, you will complete a 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 block 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. You may continue to talk with your mentee, but you will not be expected to do so, nor will you need to maintain a study diary if you do. If you agree to be assigned a second mentee, you will repeat the process above for your second 16-week-long mentoring intervention.

Mentor Supervision Group Meetings:

While you are participating in this study, you will be given the option of meeting together with the other peer mentors and the study team for periodic supervision groups, similar to a caregiver support group. The study team will lead each session and will start with introductions and any updates on the study. The study team will ask each mentor to share how his or her experience with mentoring has been so far. Mentors will be asked to describe the topics he or she has covered with the mentee, which topics and resources seemed to be helpful and which were not. Mentors will be asked to share concerns of unmet needs discussed by their mentees. Mentors will share helpful strategies with each other.

How long will you be in the study?

You will be in the study for approximately one year, starting with an initial five-hour training session conducted at Rush. You will then be matched with a mentee with whom you will have weekly visits of at least 30 minutes each for 16 weeks (4 months).. The weekly visits may be in person, by telephone call, or by videoconferencing (such as FaceTime). You will be asked to complete one or two of these 16-week blocks of peer mentoring. Depending on study needs and your availability, you can be paired with up to two mentees at any time during your participation. The period of time between blocks of active mentoring may be up to 4 months. While you are participating in this study, you will also be given the option of attending mentor supervision groups by phone, by videoconferencing, or in person.

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 is a risk of fatigue or emotional stress when serving as a mentor. The study team has designed the mentor training, check-in phone calls or emails, and supervision group meetings to minimize these risks and to address them should they arise. You may experience mild boredom or cognitive fatigue from the initial caregiver peer mentor training session; however, most individuals find the training material and session interesting, relevant, and informative.

You may feel uncomfortable sharing information about yourself or your loved one with a person who you do not know, however the mentees are all 1) current caregivers who are in similar situations caring for their own loved ones with PD; 2) instructed by the study team to respect confidentiality.

Are there benefits to taking part in the study?

The potential benefits to subjects are as follows: (1) validation of your experiences and accumulated knowledge as a caregiver to a loved one with PD, providing some potential degree of closure and purpose. (2) You may have previously been involved with other caregivers but become disconnected if/when your loved one with PD passed away, and by attending the mentoring supervision groups, may rejoin the caregiver community and get benefits from social interactions and shared experiences.

The potential impact of this and future studies is a model of care to improve quality of life and caregiver strain for hundreds of thousands of individuals with PD and related disorders. The potential benefit to society includes: (1) increasing the independence, quality of life, and productivity of patients with PD and related disorders, (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, (7) reducing caregiver depression and anxiety, (8) improving caregiver and mentor self-efficacy, and (9) decreasing use of available healthcare resources and costs. In our opinion, the individual and societal benefits clearly outweigh the minimal risks of participation in this study.

What other options are there?

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

- You may choose to participate in caregiver support groups or bereavement support groups, if applicable, at or outside of Rush University Medical Center.

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 training, phone check-ins, mentoring diaries, and supervision groups. 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.

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 or rewards for being in this study. If you live within 60 miles of Rush, we will provide you with roundtrip subway passes or parking passes to attend the mentor training session and the mentor supervision groups. If you live more than 60 miles from Rush, you will be reimbursed up to $585 to cover the cost of a flight, ground transportation to/from the airport, and a one-night hotel stay to attend the mentor training session.

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.

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.