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Learning to PERSEVERE: Peer Mentor Support and Caregiver Education in Lewy Body Dementia

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Rush University Medical Center

Title: Learning to PERSEVERE: Peer Mentor Support and Caregiver Education in Lewy Body Dementia
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ABBREVIATIONS

AD	Alzheimer's Disease
DAS	Dementia Attitudes Scale
GDS-SF	Geriatric Depression Scale – Short Form
HADS	Hospital Anxiety and Depression Scale
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICF	Informed Consent Form
LBD	Lewy body dementia
PD	Parkinson's Disease
PDD	Parkinson's Disease Dementia
PDQ-Carer	Parkinson's Disease Carer Questionnaire
PERSEVERE	Peer mentor support and caregiver education
SCT	Social Cognitive Theory
ZBI-12	Short Zarit Burden Interview

I. Project Rationale and Description

I.a. Purpose of the Study

Dementia is one of the most common and expensive conditions worldwide, with nearly 44 million people diagnosed, costing approximately $1 trillion worldwide[1]. Lewy body dementia (LBD) is the second most common major neurocognitive disorder, comprising Parkinson's Disease (PD) dementia and Dementia with Lewy Bodies. LBD causes deterioration in multiple cognitive, motor, and neuropsychiatric domains, leading to heavy reliance on family caregivers[2–6]. As LBD progresses, patients are prone to complications resulting in emergency room visits, hospitalizations, and institutionalization[7–9]. Annual health care costs are nearly one third higher in LBD compared with Alzheimer's Disease, driven primarily by hospitalizations for falls, neuropsychiatric symptoms, and infections, which are often preventable or treatable at home if recognized early[8,10]. LBD patients experience prolonged hospital stays, increased in-hospital mortality, and a fivefold higher risk of institutionalization, where they suffer suboptimal care and excess mortality[9,11–17]. Caregivers are uniquely positioned to identify and manage complications at home, preventing functional decline and emergencies. Yet simultaneously, caregiver strain is an independent risk factor for hospitalization and institutionalization in LBD[8,9,18]. Few interventions have addressed caregiver strain or mastery in this population[3–6,8].

In response to this knowledge gap, we piloted peer mentoring for caregivers of homebound patients with advanced PD, nested within a trial of interdisciplinary home visits (K23NS097615). This intervention included a five-hour educational workshop among 34 mentors. We matched mentors with caregiver mentees for 16 weeks, and interim analyses of mentees completing the program indicate feasibility and acceptability.

We now propose to adapt, improve, and implement a **pe**er mentor **s**upport and car**egiv**er **e**ducation (**PERSEVERE**) intervention for LBD caregivers. We will conduct focus groups and interviews with pilot mentors, mentees, and current caregivers to generate feedback on the mentoring curriculum and handbook. We will focus on key areas of LBD caregiving mastery, including: fall prevention, detecting and managing infections, neuropsychiatric symptom management (particularly hallucinations, delusions, delirium, anxiety, and depression), and advance directives. Applying the stress process model of caregiver strain[19], enhanced by feedback and behavior change theories[20–23], we will revise the mentor training curriculum, conversation guides, and resource handbook to operationalize LBD caregiving mastery for the key areas above. We will recruit and train a cohort of approximately 30 LBD peer mentors using the revised curriculum, developing their capacity to serve as LBD caregiving mastery coaches. We will assess mentors' caregiver mastery using Pearlin and Schooler's scale pre- and post-training[19]. Finally, we will match each mentor with an active LBD caregiver for 16 weeks of peer mentoring using our revised conversation guides and handbook to assess the impact of mentoring on caregiver mastery, strain, anxiety, and depression.

We will pursue the objectives above with the following specific aims:

Aim 1: To operationalize caregiving mastery in LBD, focused on fall prevention, infection and neuropsychiatric symptom management, and advance directives.

H_1: By conducting focus groups and interviews with former and potential LBD mentors and mentees, we will refine a practical toolkit, including a training curriculum, resource handbook, and conversation guide.

Aim 2: To test the impact of peer mentor training on LBD caregiver mastery.

H_2: Mentors will demonstrate greater caregiver mastery following training, as demonstrated by improved caregiver mastery and LBD knowledge scores compared to baseline.

Aim 3: To assess the impact of peer mentoring on LBD caregiver mentees.

H_3: Family caregivers of patients with LBD will demonstrate increased caregiving mastery, LBD knowledge, and improved social support, after 16 weeks of structured peer mentoring.

This work will identify key features of caregiving mastery and support in LBD, refine and validate a caregiver support toolkit, and test the impact of a theory-driven intervention to mitigate adverse caregiver outcomes.

I.b. Background

PD affects nearly one million individuals in the US, with a 77% projected increase in prevalence by 2030[24]. With increasing age and PD duration, the prevalence of PD Dementia (PDD) approaches 70%[25,26]. Conversely, 4.2 to 7.5% of *all* individuals with dementia will be diagnosed with DLB[27]. DLB and PDD differ in chronology but share similar underlying pathology and neuropsychiatric features—particularly, depression, anxiety, delusions, and hallucinations—hence the umbrella classification of LBD[28]. As LBD progresses, symptoms increase in number and severity, quality of life worsens, and hospitalizations and caregiver strain increase[3,29,30].

The leading causes of hospitalization in LBD are falls, urinary incontinence or infection, dehydration, and neuropsychiatric changes, many of which are preventable or treatable at home if recognized and addressed promptly[12]. An independent but related risk factor in both hospitalization and institutionalization in LBD is caregiver strain[4,8,9]. Once hospitalized or institutionalized, people with LBD suffer excessive iatrogenic morbidity and mortality[12]. Despite overwhelming evidence linking caregiver strain to both acute healthcare utilization and to adverse caregiver health consequences[32], and despite unmet needs for prognostic counseling and education for LBD caregivers, few interventions have targeted caregiver strain in this population[31–33].

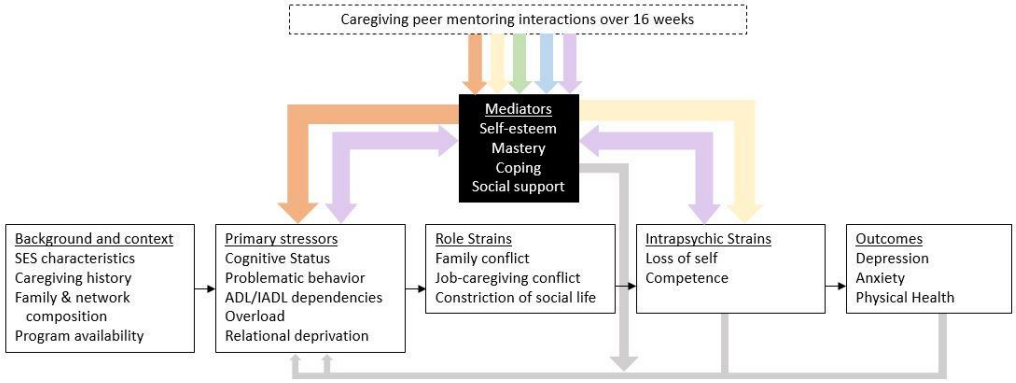
Early studies matched Alzheimer's Disease (AD) caregivers with peer mentors—former informal AD caregivers—to bolster coping skills and social support[34–36]. Qualitative data showed benefits for caregivers and mentors, though some quantitative results are equivocal due to variable implementation[34,37]. There is a knowledge gap regarding the content, logistics, and implementation of peer mentorship, and LBD caregivers face different and greater challenges than their AD parallels[38]. While peer mentorship yields social support, this may be necessary but insufficient as it does not address other contributors to caregiver strain[39].

Caregiver strain and comorbidities have been conceptualized in the Stress Process Model such that *background and context*, *primary stressors*, *role strain*, and *intrapsychic strains* interact to yield outcomes of *caregiver stress and strain*, including depression, anxiety, and physical and psychological comorbidities[39]. Proposed mediators of these relationships are social support, coping, and *mastery*—both competence and confidence as a caregiver[21]. Indeed, Mausbach and colleagues have demonstrated that mastery attenuates the relationship between caregiver stress and depressive symptoms[20,40].

We have designed a theory-based intervention of targeted education on common causes of hospitalization in LBD patients, combined with social support from trained peer mentors**,** to enhance caregivers' mastery and LBD knowledge. Social Cognitive Theory (SCT) proposes that behavior change is dynamic, affected by expectations, observational learning, and reciprocal influences from the environment[23]. Figure 1 shows how PERSEVERE applies SCT constructs to the revised Stress Process Model to improve caregiving mastery and ultimately, outcomes. PERSEVERE builds on our pilot framework, qualitative analysis of focus group feedback, and existing LBD and dementia caregiving educational materials.

Preliminary data: The study team is currently completing a study of caregiver peer mentoring in caregivers of patients with PD (Rush IRB # 17080209, PI: J. Fleisher). During three five-hour sessions, our team trained 34 caregiver peer mentors who were matched with caregivers of 65 homebound PD patients participating in an ongoing home visit trial. Caregivers were matched with a mentor at home visit 2 and consented to weekly mentoring calls between visits 2 and 3 (~16 weeks). This study has demonstrated the feasibility of this type of peer mentoring program: among 48 caregivers receiving mentoring, 35 have completed the program to date. Those completing the program had a median of 13 mentoring calls (IQR 7.5) with 98% of caregivers finding visits useful, 99% getting along with their mentor, and a wide range of topics covered, from resources to coping strategies. The NIH K23 trial is ongoing. We will analyze change from baseline in caregiver strain, self-efficacy, anxiety, and depression upon study completion. We will also analyze secondary outcomes including changes within mentors themselves.

Figure 1. Conceptual Model of PERSEVERE Interaction and Social Cognitive Theory Constructs with Stress Process Model



Concept	Definition	Illustration
Reciprocal determinism	Bi-directional interactions and influences of individual behavior and environment	Heightened caregiver anxiety and attention to consequences of falls can increase patient's fear of and likelihood of falling, increasing caregiver anxiety. Mentors address these relationships, provide strategies for positive interactions.
Behavioral capability	Knowledge and skills to carry out behavior	Mentors can provide step-by-step "How To" guides and checklists for items such as "coping with sudden mental status changes" or "starting a conversation about advance directives"
Expectations	Anticipated results of behavior	Mentors provide context about problem behaviors and risks of hospitalization, but can help shift expectations from unavoidable to potentially avoidable and manageable
Self-efficacy	Beliefs about personal ability to accomplish behavior change	Mentors, through structured curriculum, interactions, and reflections on mentee's responses, will bolster mentee's self-efficacy
Observational learning (modeling)	Learning via observation of the experiences of others	Mentors will reflect on their *own* real-life caregiving challenges, successes, and how this translated to their own mastery and outcomes
Reinforcements	Responses to behavior that affect the likelihood of repetition	Caregivers will reflect on how they successfully managed problematic patient behaviors/sudden changes, or mentor will point out and celebrate successes, prompt caregiver on how to reinforce for future

I.c. Study Design

Overview: The aims of this study are to 1) operationalize caregiving mastery in LBD, focused in fall prevention, infection and neuropsychiatric symptom management, and advanced directives; 2) test the impact of peer mentor training on LBD caregiver mastery; and 3) assess the impact of peer mentoring on LBD caregiver mentees. We will address these goals by **Aim 1**: convening focus groups with stakeholders to obtain feedback on the existing mentoring curriculum and to reflect on key areas of LBD caregiving mastery for incorporation in the revised curriculum. We will then revise the PERSEVERE curriculum and handbook based on feedback and incorporation of LBD-specific and dementia-relevant educational materials for both social support and LBD mastery education. **Aim 2:** To test the impact of the peer mentor training on LBD caregiver mastery, we will assess participating mentors' caregiver mastery and LBD knowledge before and after participation in an 6-7 hour mentor training session. **Aim 3:** The trained mentors will be matched with family caregivers of patients with LBD and complete a 16-week, structured peer mentoring program. We will compare change in caregiver mastery and LBD knowledge between baseline and 16 weeks of social support and education through mentoring calls.

II. Characteristics of the Research Population

II.a. Number of Subjects

Total Number of Subjects: 896 total participants in four different categories: 30 focus group participants (across multiple focus groups, depending on scheduling needs), 800 participants in the online recruitment survey, 36 peer mentors, and 30 caregiver mentees

Focus group participants*:* 30 participants who will each participate in one focus group of up to 10 participants

Peer mentors*:* 36 non-professional current or former caregivers (allowing for the dropout of up to 6 mentors)

Caregiver mentees: 30 current non-professional caregivers

Online Recruitment Survey Participants: 800 current caregivers

Power Calculation: This is a pilot study, intended to generate data regarding effect sizes and to inform sample size calculations for a larger, multi-centered randomized controlled trial in the future. Thus, our sample size of 30 mentees is based on historical recruitment to the preceding K23 and anticipated projections for recruitment within the time frame of this one-year grant. Working backwards from 30 mentees requiring a matched mentor and accounting for up to 15% dropout of mentors after training, we will enroll 36 mentors.

II.b. Gender of Subjects

There will be no exclusion of subjects based on gender.

II.c. Age of Subjects

Subjects will be 21-90 years old.

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 study due to the general lack of appropriately translated study assessments and to ensure clear communication between mentors and mentees participating in the mentor program.

II.e. Inclusion Criteria

1. **Focus group participants**
    a. Each subject must be 21 years of age or older. A subject may identify as any sex, any race, and any ethnicity.
    b. Subjects must be either:
        i. Individuals who served as peer mentors in our previous study of caregiver peer mentoring and completed at least 16 weeks of mentoring.
        ii. Individuals who were caregiver mentees in our previous study of caregiver peer mentoring who completed 16 weeks of mentoring.
        iii. Current informal family caregivers of community-dwelling LBD patients in the Chicago area, recruited from Rush University System for Health and Advocate Aurora Health, who have *not* participated in mentoring.
    c. Each subject must be primarily English-speaking.
    d. Each subject must be willing and able to attend a virtual, online focus group via an internet- and video-camera-equipped computer, tablet, or smartphone.

2. **Peer mentors**
    a. Each subject must be 21 years of age or older. A subject may identify as any sex, any race, and any ethnicity.

b. Each subject must be a non-professional caregiver (defined as *cohabitating with or spending ≥10 hours weekly on unpaid caregiving duties*) of LBD patients. Mentors may participate regardless of their loved one's status (living at home, institutionalized, or deceased).
    i. If mentors also receive compensation for a portion of their time spent on caregiving duties through state or community programs, they may participate as long as they cohabitate or spend ≥10 hours providing unpaid care to their loved one.
c. Each subject must have:
    • >2 years of LBD caregiving experience, or
    • >2 years of PD caregiving experience for an individual without cognitive impairment and professional or volunteer experience interacting with individuals with cognitive impairment or dementia, or their caregivers (e.g., support group leader, healthcare professional, counselor, social worker), or
    • >4 years of PD caregiving experience for an individual without cognitive impairment
d. Each subject must be primarily English-speaking.
e. Each subject must have a working email address and internet access.
f. Each subject must have a working telephone number at which he or she can be reached and which he or she is willing to share with the matched mentee.
g. Each subject who will attend an online peer mentor training session must have an internet- and video-camera-equipped computer, tablet, or smartphone.

3. Caregiver mentees

a. Each subject must be 21 years of age or older. A subject may identify as any sex, any race, and any ethnicity.
b. Each subject must be a non-professional, unpaid caregiver, as defined above in II.e.2.b., of a community-dwelling LBD patient.
c. Each subject must be interested in improving their caregiving mastery.
d. Each subject must be primarily English-speaking.
e. Each subject must have a working email address and internet access.
f. Each subject must have a working telephone number at which he or she can be reached and which he or she is willing to share with the matched mentor.

II.f. Exclusion Criteria for all Subjects

1. Subjects exhibiting symptoms of a severe psychiatric disorder interfering with their ability to participate in the study, as determined by a study team member or the PI.
2. Subjects who are primarily non-English-speaking.
3. Terminal illness (life expectancy of < 12 months).

II.g. Vulnerable Subjects

This study will not include children, prisoners, and homeless persons. Participants are not expected to have cognitive impairment, however as it is anticipated that many subjects may be elderly and at risk of age-related cognitive changes as well as neurodegenerative disease, all subjects will be assessed for capacity to consent (see Section V.b.). The consent form will state that participation in our study will *not* affect their loved one's clinical care.

II.h. Online Recruitment Survey Participants

These participants will include individuals who elect to complete an online survey in order to indicate their interest and eligibility to participate in a caregiver peer mentor program.

III. Methods and Procedures

III.a. Aim 1: Subject Identification, Recruitment, Consenting and Study Procedures

Subjects participating in focus groups and interviews will be recruited from 3 different populations: 1) individuals who were caregiver mentees in our previous peer mentoring study, 2) individuals who served as peer mentors and completed 16 weeks of mentoring in our previous peer mentoring study, and 3) individuals who are current informal family caregivers of community-dwelling LBD patients in the Chicago area, recruited from Rush University and Advocate Aurora Health, who have *not* participated in mentoring. A study team member will provide potential participants with information about the research study by reading from an IRB-approved recruitment script. Once they understand study requirements and the schedule of events, have expressed interest in participating and been screened for eligibility, their focus group or interview will be scheduled.

If an individual does not meet eligibility criteria, the study team will maintain a list of screened and ineligible individuals containing only the individual's sex, age, race, ethnicity, and responses to the eligibility criteria that rendered the individual ineligible for the purposes of ensuring adequate representation of minority populations in our recruitment and for documentation to the sponsor. Names or other identifiers will not be maintained on this list, and only aggregated, de-identified data will be shared with the sponsor in regards to screened and ineligible individuals. If an eligible individual chooses not to participate in the study between the time of the screening phone call and the initial study visit, that individual's de-identified information will be stored as above, similar to screened and ineligible individuals

Given the COVID-19 pandemic, we will conduct virtual focus groups/interviews using a password-protected videoconference platform such as Zoom. The informed consent process will take place online via REDCap prior to the focus group/interview date. In this way, participants can contact the study team with any questions or concerns prior to the start of the focus group/interview. After participants have read the online consent form and indicated they are willing to participate, they will complete capacity assessment questions (see Section V.b.) to ensure understanding of the consent process.

Focus groups/interviews will be led by a qualified neuropsychologist and psychometrician (GS), using focus group manuals that include open-ended probes based on SCT constructs and the stress process model. The aim of these focus groups/interviews is to revise and improve upon our previous peer mentor program's curriculum. During the focus group or interview, participants will be presented with the previous program's curriculum, including training slides and the mentor handbook. We will also provide a variety of proposed educational resources for inclusion in the revised curriculum and obtain participants' feedback. We will also seek input from participants on the development of a mentoring preferences survey for both mentors and mentees to optimize mentor matching in Aim 3. These focus groups/interviews will be recorded and transcribed, with all identifying information stripped from the transcripts prior to analysis.

III.b. Aim 2: Subject Identification, Recruitment, Consenting and Study Procedures

We will recruit peer mentors by contacting facilitators of LBD support groups and asking them to distribute IRB-approved recruitment fliers, placing recruitment fliers in the waiting area of Rush University's Parkinson's and

Movement Disorders Program (including locations at Rush University Medical Center, Rush Copley, and Rush Oak Park, given the presence of movement disorders specialists at each location), distributing recruitment fliers at community events, asking national organizations such as the Parkinson's Foundation and the Lewy Body Dementia Association to distribute recruitment fliers by mail, email or social media, asking national organizations such as the Parkinson's Foundation and the Lewy Body Dementia Association to post a social media recruitment survey on social media platforms such as Facebook and Twitter that interested and eligible individuals can complete to indicate their potential interest in studies of caregiver peer mentoring, sending potential participants the recruitment flier via MyChart , contacting individuals referred to the program by providers at Rush or other institutions in the Chicago area, and contacting mentors and mentees who participated in the previous mentor program who might be interested in serving as a mentor in this program. Interested participants will be given study information and screened for eligibility to exclude potential mentors who do not meet inclusion criteria, who express discomfort discussing sensitive topics with their potential mentee (including, but not limited to, challenges faced in their own caregiving journey, advance directives, or cultural differences between the mentor and mentee), or whose expressed belief systems would suggest inability to deliver the curriculum.

Mentors will attend one 6-7 hour training session, either held in-person at Rush University or a via password-protected videoconferencing application, such as Zoom. Study expectations and logistics will be reviewed with each potential mentor prior to the training session via phone. For all subjects, regardless of whether they attend an online or in-person training session, the informed consent process will take place online via REDCap prior to the training session date. In this way, participants can contact the study team with any questions or concerns prior to the training session. After participants have read the online consent form and indicated they are willing to participate, they will complete capacity assessment questions (see Section V.b.) to ensure understanding of the consent process.

Individuals may refuse to participate in the study and leave the peer mentor training session at any time. At the beginning of the training session, baseline data will be collected either via printed pen-and-paper assessments, or via online surveys (demographics, mentoring preferences, mastery scale, LBD knowledge test, Dementia Attitudes Scale (DAS); see Section III.d. for details). Next, mentors will receive training regarding topics including active listening, mentoring, goal-and boundary-setting, an overview of LBD, risk factors for hospitalization, impact on caregiver, practical approaches to symptom management, and caregiving issues. The study team will then present the new PERSEVERE curriculum and accompanying handbook. The study team will solicit questions and lead role-play conversations. Finally mentors will complete post-training assessments (mastery scale, LBD knowledge test, DAS) and will receive a training stipend (either directly from study team members if in-person, or mailed/emailed if completing training virtually).

III.c. Aim 3: Subject Identification, Recruitment, Consenting and Study Procedures

We will recruit caregiver mentees by contacting facilitators of LBD support groups and asking them to distribute IRB-approved recruitment fliers, placing recruitment fliers in the waiting area of Rush University's Parkinson's and Movement Disorders Program (including locations at Rush University Medical Center, Rush Copley, and Rush Oak Park, given the presence of movement disorders specialists at each location), distributing recruitment fliers at community events, asking national organizations such as the Parkinson's Foundation and the Lewy Body Dementia Association to distribute recruitment fliers by mail, email or social media, asking national organizations such as the Parkinson's Foundation and the Lewy Body Dementia Association to post a social media recruitment survey on social media platforms such as Facebook and Twitter that interested and eligible individuals can complete to indicate their potential interest in studies of caregiver peer mentoring, sending potential participants the recruitment flier via MyChart, and contacting individuals referred to the program by providers at Rush or other institutions in the Chicago area. A study team member will call interested caregivers to provide them with study

information and logistics by reading from an IRB-approved recruitment script. If interested, the team member will email the caregiver a link to the electronic informed consent and baseline survey in REDCap. The components of the informed consent document will appear on the first page of the online survey. Potential participants 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 will incorporate capacity assessment questions to ensure understanding of the consent process. Upon correct completion of these questions, the participants will be directed to begin the actual survey questions. Participants will be asked to complete a demographics survey, a survey describing the characteristics of the LBD patient for whom they are caring, and a mentoring preferences survey to facilitate matching (see Section II.d. for details). As recruitment for mentees will be rolling and occurring during mentor recruitment and training, there may be lag time between ICF completion and mentoring intervention of weeks to months, and this will be clearly communicated to participants during the screening phone calls and reiterated in the ICF.

Once Aim 2 (above) is complete and 36 mentors have been trained, caregiver mentees will be matched with mentors by relationship to LBD patient, then by sex and age, as much as possible. Mentor and mentee preferences expressed in the mentoring preferences survey will be honored to the extent that the study team is able given the available mentor and mentee participants. The study team will contact mentees once a match is available for them. First, the study team will direct the mentee to complete baseline primary and secondary outcome assessments online via REDCap, including: mastery scale[19], LBD knowledge test, loneliness scale[41], Short Zarit Burden Interview (ZBI-12)[42], Hospital Anxiety and Depression Scale (HADS)[43], Geriatric Depression Scale – Short Form (GDS-SF)[44], and Dementia Attitudes Scale (DAS)[45] in order to obtain their pre-intervention baseline. The study team will then provide the mentee with contact information for their mentor, and caregivers will be mailed the PERSEVERE handbook.

Mentor-mentee pairs will then begin the 16-week peer mentor program. During this time, pairs will be expected to speak for ≥15-30 minutes weekly, and to review that week's PERSEVERE topics in the handbook before or during each call to facilitate meaningful conversations. Discussions are not scripted and will not necessarily be limited to that week's topics, at the discretion of the participants. Mentors and mentees will complete online study diaries every 2 weeks, assessing intervention fidelity. Up to 3 email reminders will be sent and/or up to 3 phone calls attempted to complete each study diary. Diary entries will include information such as call frequency, duration, topics discussed, and concerns. At the Week 8 or Week 10 survey, all mentees and those mentors who are still actively caregiving for a loved one with LBD will complete the Parkinson's Disease Carer Questionnaire (PDQ-Carer), a novel measure of PD-specific caregiver quality of life. Mentors will participate in 4 recorded monthly conference calls to share successes, challenges, and feedback, and to ask questions of and be supported by the study team.

Upon completion of the 16-week mentor program, mentors and mentees will be sent a link to complete post-mentoring assessments online (mentors: mastery scale, LBD knowledge test, DAS, PDQ-Carer; mentees: mastery scale, LBD knowledge test, loneliness scale, ZBI-12, HADS, GDS-SF, DAS, PDQ-Carer, and fall frequency and healthcare utilization of their loved one; see Figure 3).

Figure 3. Outcomes, Fidelity Metrics, Covariates, and Confounders in Aims 2 & 3

	Aim 2 - Mentor Training	Aim 3 – PERSEVERE Pilot
Primary Outcomes	• Mastery scale[19] • Multiple-choice LBD knowledge test	• Mastery scale • LBD knowledge test • Loneliness scale[41]
Secondary Outcomes	• Mastery Scale (after mentoring) • Dementia Attitudes Scale (DAS)[45] • Parkinson's Disease Carer Questionnaire (PDQ-Carer)	• Short Zarit Burden Interview (ZBI-12)[42] • Hospital Anxiety and Depression Scale (HADS)[43] • Geriatric Depression Scale – Short Form (GDS-SF)[44] • DAS

Fidelity Metrics	(only if actively caregiving for loved one with LBD)	• Parkinson's Disease Carer Questionnaire (PDQ-Carer)
		• Frequency and duration of calls • Number of missed calls/weeks • Coverage of target topics; other topics discussed • Qualitative feedback in mentor conference calls • Dropout rate and reason
Demographics, Confounders, Covariates	Sex, age, race, ethnicity, education, comorbidities, caregiving relationship, duration of caregiving; patient's disease duration, stage, ADLs[46] and IADLs[47] at baseline, and patient's monthly frequency of falls and acute healthcare utilization (combined number of ER visits not yielding admission + hospital nights) in the months prior to and during the intervention.	

III.d. Assessments

All participants who agree to be part of the study and sign the informed consent form will be asked to complete a series of surveys and assessments. There is no known risk associated with completion of these assessments. All or some of the following measures may be administered but are not limited to:

- *Mastery Scale:* A 7-item scale measuring the extent to which a participant sees life as being under his/her personal control vs. something that is fatalistically ruled. Scores range from 7 to 28, with higher scores indicating greater levels of mastery.[19]

- *LBD Knowledge Test:* A multiple-choice test created by the study team to assess participants' level of knowledge of LBD. Higher scores indicate a greater degree of knowledge of LBD and its effects. This assessment will be based on the revised PERSEVERE curriculum following the conclusion and analysis of data from focus groups.

- *Dementia Attitudes Scale (DAS):* A validated, 20-item scale measuring participants' attitudes toward dementia and individuals with dementia. Scores can range from 7-140, with higher scores indicating more positive attitudes.[45]

- *Loneliness Scale:* A 3-item, validated measurement of a participant's feelings of isolation or disconnectedness. Scores can range from 3-9, with higher scores indicating greater loneliness.[41]

- *Short Zarit Burden Interview (ZBI-12):* A 12-item, validated measurement of caregiver burden in older adults. Scores range from 0-48, with higher scores indicating greater caregiver burden.[42]

- *Hospital Anxiety and Depression Scale (HADS):* Brief, 14-item highly validated scale for measuring anxiety (7 items) and depression (7 items), where scores of >8 for either anxiety or depression indicate probable symptoms.[43]

- *Geriatric Depression Scale – Short Form (GDS-SF):* Brief, 15-item, highly validated scale for measuring depression in older adults, total possible range of 0-15, where a score >5 suggests depression[44].

- *Mentoring Preferences Survey:* A survey designed by the study team, with input from focus group or interview participants (see Aim 1) that will allow for mentors and mentees to indicate matching preferences (e.g., matching with a person who likes to speak in the evenings vs. the morning, matching with someone of a specific gender, etc.)

- *Katz Index of Activities of Daily Living:* A brief, 6-item assessment that indicates the level of assistance with ADLs needed by patients for whom mentees are caring[46].

- *Lawton-Brody Instrumental Activities of Daily Living Scale:* an 8-item assessment that indicates the level of assistance with IADLs needed by patients for whom mentees are caring[47].

- *Parkinson's Disease Carer Questionnaire:* a 29-item, validated assessment measuring 4 domains of quality of life specific to unpaid/family caregivers of individuals with Parkinson's Disease (Jenkinson et al 2012, Jenkinson et al 2013).

III.e. Data Analysis and Data Monitoring

I. Statistical analysis: The primary data will be entered into a HIPAA-compliant database (REDCap)[48], with quarterly audits for fidelity. Data will be exported to Stata 15 for analysis. Primary and secondary outcomes, covariates and confounders, and fidelity metrics are listed in Figure 2.

II. **Aim 1 (focus groups/interviews, PERSEVERE curriculum development):** We will describe baseline demographics of focus group participants, transcribe recordings, and develop a theme codebook. Framework analysis[49] will be used to guide the revision of the structured, 16-week mentoring curriculum, with provision of practical checklists, goal setting, and step-by-step guides for key areas of LBD caregiving mastery in addition to social support. Several topics in the revised curriculum will be repeated or given two weeks to allow for reiteration in the event of missed mentoring calls.

III. **Aim 2 (peer mentor training, LBD caregiver mastery):** We will describe the demographics, baseline mastery, LBD knowledge, and dementia attitudes of mentors pre-training, assessing for normality and reporting means/standard deviation or medians/interquartile range. We will compare within-subject change in mastery, LBD knowledge, and DAS pre- and post-training (primary outcomes) and pre-training and post-mentoring (secondary outcomes) using paired t-tests or Wilcoxon sign rank test, as appropriate.

IV. **Aim 3 (caregiver peer mentoring):** We will analyze data fidelity by summarizing categorical variables by frequencies and percentages and will assess continuous variables for normality, summarized by mean/standard deviation or median/interquartile range. We will describe the baseline demographics, patient characteristics (including fall frequency and acute healthcare utilization), mastery, LBD knowledge, loneliness, ZBI, HADS, GDS-SF, and DAS of caregivers. Bivariate analyses will compare change between baseline and 16 weeks of mentoring in each of the above, using paired t-test or Wilcoxon sign rank, as appropriate. We will also compare change in PDQ-Carer between mid-study and Week 16 as an exploratory outcome. To examine potential covariate effects, we will run a series of repeated measures ANCOVAs for pre- and post- primary and secondary outcome measures using demographic and confounder variables as nuisance variables. These analyses will be considered exploratory due to the loss of degrees of freedom resulting from the covariates. Mentor program fidelity metrics including *dropout rate and reasons, time* spent on phone calls, *number* of phone calls, and *topics* discussed will be calculated

based on responses obtained from biweekly online study diary entries. Qualitative data will be gathered from the monthly mentor conference calls via notes taken by the study team; framework analysis will be applied to identify key themes regarding successes, challenges, and recommendations for improving the program.

V. **Monitoring and Oversight:** PERSEVERE will be maintained by the Principal Investigator. The Principal Investigator will review study procedures annually and report any concerns in the IRB continuing 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 as Research Electronic Data Capture (REDCap)[48]. 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 for: Subject accrual (including compliance with enrollment criteria); Status of all enrolled subjects; Adherence data regarding study activities and procedures. Any issues noted during the quarterly data and safety monitoring reviews will be submitted to the IRB annually. 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. There are no predefined stopping rules for the overall study.

III.f. Data Storage and Confidentiality

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, informed consent forms and informed consent documentation checklists, and de-identified notes taken by the study team during the focus groups and interviews, mentor training, or mentor program conference calls. 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. The notes taken by the study team will be reviewed for any errant identifying data on a monthly basis and censored, and the original hard copies of such notes will be stored in a locked file cabinet in the PI's office.

All subjects (focus group/interview participants, mentors and mentees) will be assigned unique ID numbers.

Only the PI, Co-investigators and research staff will have access to the database. During the consent process, the potential participant will be informed that aspects of their PHI will be shared with collaborating researchers at Rush; 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. 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 this 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 the completing the surveys and assessments that we will use in this study. Subjects completing these types of surveys and assessments may experience mild boredom or cognitive fatigue. Subjects participating in the focus groups or training session may also experience mild boredom or cognitive fatigue. There is a risk of loss of confidentiality by participating in this study, however the study team will take all reasonable precautions to secure the data and maintain confidentiality as described above. Due to the nature of focus groups and group training sessions, confidentiality of information shared cannot be guaranteed; however, the study team will emphasize to all participants that any information discussed should not be shared outside the group. Mentors will be instructed during mentor training about the importance of confidentiality of mentoring conversations, and this will be reiterated in the handbook for both the mentors and mentees.

IV.b. Potential Benefit to Subjects

Focus group or interview participants: The potential direct benefits to focus group participants include the satisfaction of having contributed to scientific knowledge about LBD and related disorders that may help to improve the quality of life for themselves and other subjects' loved ones with movement disorders. For participants who were previously involved in other support groups or mentor programs, the focus groups may provide positive social interactions with other caregivers and feelings of validation.

Caregiver peer mentors: The potential direct benefits to caregiver peer mentors include validation of their lived experiences and accumulated knowledge as caregivers to a loved one with LBD, providing some potential degree of closure or purpose. Caregiver peer mentors may have previously been involved with other caregivers but become disconnected if/when their loved one with LBD passed away, and by attending the mentor training session, establishing a mentoring relationship, and participating in conference calls, may rejoin the caregiver community and derive benefits from social interactions and shared experiences.

Caregiver mentees: The potential direct benefits to mentees include increased mastery due to the relationship and discussions held with their mentor, decreased depression, anxiety, and caregiver strain due to the positive relationship with emotional support from a caregiver peer mentor.

All subjects: All subjects' involvement will contribute to scientific knowledge determining whether a formal, 16-week mentoring program can have an impact on caregiver mastery, strain, anxiety, and depression. This study and future studies may provide a model of care to improve quality of life and caregiver strain for hundreds of thousands of individuals with LBD and related disorders.

V. Subject Consent

V.a. Process of Consent

All focus group and mentor program participants will complete the informed consent process online via REDCap after the study is explained to them and questions are answered by a member of the study team. Informed consent must be completed prior to any participant joining any portion of the study (focus groups, mentor training, or beginning the peer mentor relationship). Participants will be asked to give online consent for the study by trained study team members (PI or co-investigators, the latter of which will be trained by the PI in the process of assessing capacity and obtaining informed consent)**.** Subjects completing the online recruitment survey will follow a link posted to social media by national organizations such as the Parkinson's Foundation and the Lewy Body Dementia Association. Before providing consent, online survey participants will be given the contact information of the study team and asked to contact the team if they have any questions before providing consent. Subjects are not expected to have cognitive impairment, however, subjects may be elderly and at risk of age-related cognitive changes, so all subjects will be assessed for capacity to consent. The study team has prior experience building capacity assessments into REDCap online surveys.

V.b. Subject Capacity

Capacity to consent will be assessed by a designated trained research staff member and/or the PI. Designated study staff will undergo individualized training with the PI in the process of capacity assessment and informed consent, in addition to all applicable research training in the capacity and consent processes available at Rush University. The study staff have experience building capacity assessments into REDCap online surveys, such that the potential participants will be prompted during the online consent process with questions to assess the participant's comprehension by asking the participant to identify key elements of the consent form, particularly the sections of the consent form that explains what specifically they are being asked to do, how long they will be involved in the study, what risks and benefits are involved, how their confidentiality will be protected, and how their data will be stored for future use.

V.c. Subject Comprehension

The study team will assess comprehension during the capacity assessments and will be available by phone to answer any questions posed by the subject. Capacity assessments will be completed online for all participants.

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. This study does not involve deception and the aims and hypotheses are explicitly described to participants, so further debriefing is not necessary

V.e. Documentation of Consent

The consent will always be completed online and consent process details (e.g., timing) will be recorded in REDCap after built-in capacity assessments.

V.f. Costs to the Subject

There will be no cost to subjects associated with participation in this study.

V.g. Payment for Participation

Participants who attend the peer mentor training in person will be provided with parking vouchers or reimbursement for their subway/taxi travel (up to $20). Participants who attend a focus group or interview will receive a $50 stipend. Mentors who complete the mentor training session will receive a $50 stipend. Finally, mentors and mentees will receive $75 upon completion of the 8-week online survey and an additional $75 upon completion of the 16-week final assessment online survey.

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