Title: Social-LEAF Life Enhancing Activities for Caregivers

IRB Approved Protocol

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Improving Dementia with Lewy Bodies Care Partner Outcomes through Positive Connections

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1. PURPOSE OF STUDY

Family care partners of persons with Lewy Body Dementia (also known as Dementia with Lewy Bodies, DLB) face numerous challenges to their wellbeing including social isolation, changes in close relationships, difficult emotions, high burden of caregiving tasks and burnout. Many interventions focus on education around dementia caregiving, dementia symptom management, and dealing with negative consequences of caregiving. More recently, interest has arisen in developing strength-based interventions that seek to support family care partners discover positive emotions, self-efficacy, and meaning in caregiving.

The purpose of this study is to further this work using the Life Enhancing Activities for Family Caregivers (LEAF) intervention by adapting it to a group setting and by tying LEAF skills to social connections (Social-LEAF). We hope to display that social networks' can be used as a means of reinforcing the positive life skills of the intervention; and that these same skills will enhance social networks, increase mutual satisfaction in social interactions, and boost motivation to reach out to others, thus combatting social isolation.

In this 18-month long pilot study we hope to create a foundation for future clinical trials to test the effectiveness and mechanisms of Social-LEAF through the two main aims that will be displayed and utilized throughout the duration of this study.

Aim **1)** To understand care partner needs, preferences, concerns and optimal communication strategies to adapt the LEAF intervention to a group with social components; and Aim **2)** To determine the feasibility and acceptability of the LEAF intervention as a source of pilot data for future grants, and to assess for signs of efficacy and to identify areas where further optimization may be needed.

2. BACKGROUND AND RATIONALE

With the aging of the US and global population, the number of persons living with, and dying from, dementia is predicted to increase with an estimated 1/3 of older adults dying with dementia[1] DLB is the second most common Alzheimer's disease and related dementias, and, despite increased motor symptoms and behavioral complications, is relatively understudied[2] DLB has direct impacts on individuals, society, and our elder-care infrastructure; what tends to be less discussed is the impact of the growing number of family care partners who do the vast majority of caregiving. This impact includes lost financial opportunities, adverse effects on mental and physical health and social isolation[3]

Interference from direct caregiving hours, changing priorities, and loss of supportive from their spouse all contribute to social isolation in DLB care partners[4]. Social isolation in turn contributes to worsening of care partner outcomes, including increased caregiving stressors, poor psychological outcomes, and increased susceptibility to stress-related illnesses[5].

The majority of interventions for dementia care partners utilize psychoeducational approaches to target care partner burden, manage symptoms and address negative affect[6] While these interventions are reflective in achieving their aims, they neglect many significant opportunities to improve the care partner experience, particularly opportunities for joy, meaning and connection.

To optimally promote wellbeing, we need to go beyond merely treating diseases and eliminating suffering, to also actively promoting health and positive emotions[7] Notably positive interventions, such as the Life Enhancing Activities for Family care partners (LEAF) intervention, have been shown to increase positive outcomes (e.g. positive affect, physical health) while still addressing important negative outcomes (e.g. depression, anxiety)[8]

While positive interventions have been linked in general to prosocial behaviors and improved relationships[9] this has not been studied in the context of dementia care partner. Given the promise of positive interventions for this purpose and the pressing need for improved social support for family care partner, we see this as a critical gap with a high potential for addressing this need, impacting research in this field, and changing the clinical care landscape.

3. ADMINISTRATIVE ORGANIZATION

This study will be conducted and have the majority of its operations held at the University of Rochester Medical Center. This will include faculty in the Department of Neurology and the Center for Health and Technology (CHeT). We will also be collaborating with the Rochester Roybal STAR Center, a professor and Co-Investigator on the study at Northwestern University, the Alzheimer's Association and the Parkinson's Foundation. Dr. Moskowitz's key roles will be to offer templates for the individual interviews and pilot testing and assist in the adaptation of the intervention for Aim 1 and 2, verifying that study procedures are adequately being conducted, and help interpret the findings during data analysis and manuscript preparation.

Study Overview

We seek to adapt the LEAF intervention to a group setting and by tying LEAF skills to social connections (Social-LEAF). We hypothesize that social networks can reinforce the positive life skills of the intervention; and that these same skills will enhance social networks. In this 18-month pilot study we will create a foundation for future clinical trials to test the effectiveness and mechanisms of Social-LEAF.

4. STUDY DESIGN

This will be a completely virtual 18-month long pilot randomized control study. The initial month will be dedicated to start-up activities including IRB submission, training, database set-up and initial meetings with our internal team to review the intervention. Following this, 3 months will be towards executing the activities related to Aim 1 of the study. This will include individual interviews with up to 20 people, iterative optimization and ongoing analyses, and piloting of the Social-LEAF procedures. We will be assessing the efficacy of the Social-Leaf procedures before finalizing the intervention to implement these changes for Aim 2. Aim 1 is mainly about the interview and gaining feedback on what individuals would like to see and what they would change about the intervention. At the end of Aim 1, our team members will meet to review the transcripts and suggestions we've received. The feedback we get from Aim 1 will facilitate the study materials and final intervention for Aim 2.

Moreover, the next 12 months of the study will be focused on the execution and completion of Aim 2. This will include the implementation of the Social-LEAF interventions. Beginning with the 1:1 randomization of subjects to the intervention and waitlist control arms of the study. The intervention group starts study procedures soon after they are consented, while the waitlist control group begins study procedures 6 weeks after. Our biostatistician has provided us with a randomization program that will be downloaded into Redcap. This will allow subjects who have consented to study and entered into Redcap to be randomly assigned to the group that they will be in (waitlist control or intervention). The Social-LEAF course consists of 6 skills delivered online, through video-conferencing ("video sessions") with a trained facilitator, to help manage subject's mood and cope with the stressors of caregiving. Aim 2 subjects will complete the finalized 6-week program from the feedback we receive from Aim 1. Eligible subjects will be asked to take part in an end of study interview. The last 2 months of the proposal will be dedicated to completing data analyses/quality assurance, planning future studies, and the writing of grants, manuscripts, etc. Below, Table 1 depicts an expected timeline for the study procedures.

Table 1:

Study Procedure	**Timeline**
Study start up	0-1 Month
Aim 1	3 Months
Aim 2	12 Months

Analyses, extensions, etc.	2 Months

CHARACTERISTICS OF THE RESEARCH STUDY POPULATION

Subjects:
Overall, they must be a primary care partner of a person with DLB, have had direct contact with the care recipient at least 3 days per week (bereaved care partners can be included for this aim), be able to speak English, and be willing to participate. Subjects will be excluded if they lack the capacity to consent for themselves or have urgent supportive care needs. We are looking for up to 20 subjects for Aim 1 and 60 subjects for Aim 2.

Gender, Age, Racial, and Ethnic Origin of Subjects:
Gender and Age of Subjects:
There will be no gender-based restrictions. There will be no maximum age restriction.

Racial and Ethnic Origin: There will be no enrollment restrictions based upon race or ethnic origin. The study will include enrollment of persons of diverse racial/ethnic backgrounds to ensure that the benefits and burdens of research participation are distributed in an equitable manner.

Vulnerable Subjects
Caretaking for individuals with conditions like Dementia with Lewy Bodies (DLB) can be a strenuous task. Individuals identified by the study coordinator and/or investigator to be exhibiting characteristics of poor mental health will be addressed as soon as possible. This includes extreme responses to the questionnaires, tearfulness, signs of self-injury, etc. The coordinator will adapt ways in which to identify and approach these situations. In a more serious case, the subject will be referred to the chaplain and/or the mental health counselor on the study. Their needs and concerns are crucial to the implementation of this project.

5. INCLUSION AND EXCLUSION CRITERIA

SUBJECTS

Aim 1

- CARE PARTNER INCLUSION CRITERIA: Must be a primary care partner of a person that has been clinically diagnosed with Dementia with Lewy Bodies (DLB) or Parkinson's Disease Dementia, and has access to high-speed internet connection at home or in a location where they can speak privately with a facilitator. iPads and a hotspot will be given to those who lack internet and a sufficient mobile device but show willingness to participate. The iPads and hotspot will be returned to the study team once study procedures have concluded.

- CARE PARTNER EXCLUSION CRITERIA: Not a primary care partner of a person with DLB. Is a primary care partner of someone who has not been clinically diagnosed with DLB. Cannot provide clear and concise consent to the project.

Aim 2

- CARE PARTNER INCLUSION CRITERIA: Must be a primary care partner of a person that has been clinically diagnosed with Dementia with Lewy Bodies (DLB) or Parkinson's Disease Dementia, and has access to high-speed internet connection at home or in a location where they can speak privately with a facilitator. iPads and a hotspot will be given to those who lack internet and a sufficient mobile device but show willingness to participate. The iPads and hotspot will be returned to the study team once study procedures have concluded. Must be willing and ready to begin the intervention either immediately or in 6 weeks depending on which group they are randomly selected to be in.

    - CARE PARTNER EXCLUSION CRITERIA: Not a primary care partner of a person with DLB. Is a primary care partner of someone who has not been clinically diagnosed with DLB. Cannot speak English or provide clear and concise consent to the project.

    - INTERVENTION INCLUSION CRITERIA: Must begin LEAF procedures as soon as consented to the study. Has not taken part in Aim 1 of the study.

    - INTERVENTION EXCLUSION CRITERIA: Has not started LEAF procedures at the beginning and has taken part in Aim 1 of the study.

    - CONTROL INCLUSION CRITERIA: Will have waited the 6-week period before starting LEAF procedures after consenting and has not taken part in Aim 1 of the study.

    - CONTROL EXCLUSION CRITERIA: Has started/taken part in the LEAF procedures at the beginning and also has taken part in Aim 1 of the study.

6. RECRUITMENT METHODS

Aim 1 Recruitment Plan:
Leaders of Lewy Body Dementia support groups identified by the Parkinson Foundation or Alzheimer's Association will be contacted to assess their interest in participating in this research. We will provide information on the study goals by way of the flyers/information sheets. Interest by the group will lead to the study coordinator contacting them to schedule them for an individual interview.

Aim 2 Recruitment Plan:
Subjects will be recruited using recruitment strategies that have been successful for our ongoing studies of care partners of a family member with DLB. Including:

- Flyers to family members of patients with DLB receiving care at UR Memory Care and clinics participating in the UR Provider-Based Research Network

- Lifespan and Alzheimer's Association staff who have direct contact with older care partners in the community seeking services and interventions (who provide referrals)
- Existing research registries held by our investigators (which afford direct contact with older care partners who have previously agreed to be contacted for future research study participation).
- ResearchMatch- Potential volunteers will be sent out a contact message with a brief overview of our study which is in our IRB approved ResearchMatch form. Potential volunteers will then have an option to complete a brief pre-screening survey via a REDCap survey link and provide their contact information if they would like to be contacted about the study. The prescreening survey will screen potential subjects for age and care partner of LBD or PDD eligibility criteria.
- The Roybal STAR Center
- Foxtrialfinder (research matching service maintained by Michael J. Fox flyer on the website and interested individuals will contact the study personnel directly.
- Alzheimer's Association TrialMatch website (connects individuals living with Alzheimer's caregivers and healthy volunteers to clinical trials). https://www.alz.org/alzheimers-dementia/research_progress/clinical-trials/trialmatch
- LBDA Research Study page (Lewy Body Dementia Association website's research study page). https://www.lbda.org/research/clinical-trials/
- We will also use strategies specific to recruiting care partners for individuals with Dementia with Lewy Bodies (DLB): mailing the flyer to researchers in the Lewy Body Dementia Research Network (national network of which URMC is a Center of Excellence); newsletters and mailings through the Parkinson Foundation (international network of which URMC is a Center of Excellence); recruitment at UR Memory Care, movement disorders center and neuropalliative care clinics by clinicians. In working with UR Memory Care and Movement Disorders clinics, study coordinators may review charts for upcoming clinics and ask clinicians to provide approved study flyers to introduce the study if they feel it would be helpful and appropriate for DLB caregivers of their patients.
- In addition, we may also reach out to Recruitment Consultation, a service core of UR Clinical and Translational Science Institute (CTSI) for consultation and recruitment strategy planning to promote inclusion of racial and ethnic minority subjects.

Staff-level strategies (continuous quality monitoring and refresher trainings targeting the following):

1. Establish rapport.
2. Know the subject.
3. Guide subject with sensitivity.
4. Ongoing communications
5. Accommodations for subject needs and safety, such as transportation, safety protocols (i.e., in response to suicidal ideation, for example).
6. Focus on achievement and progress.

7. CONSENT PROCESS

Aim 1:

Potential subjects will have prior information about the study via the P.I., referrals, information sheet, flyers, and their support group leaders, etc. Once interested they will be in contact with the project study coordinator. We are requesting a waiver of documentation of consent because the research is no greater than minimal risk and the interview will be addressing a topic where written consent is not normally required. The waiver won't affect the rights and welfare of the subjects. The Roybal center will play an integral part in the determination of subject eligibility (I.e. the screening process). They will use our inclusion/exclusion criteria to view potential subjects, and if seen to be eligible by them and our criteria, they will send these subjects to the study coordinator. The coordinator will then verify their interest and eligibility by contacting them either via phone or email using the verbal script. If interest is presented and eligibility is met, the study coordinator will move forward with acquiring the subject's consent to participate. Once they have consented to participate, the project study coordinator will proceed to schedule them for an interview session.

Aim 2:

All subjects will receive some information with regard to the study via our different recruitment methods (i.e. Researchmatch), help from the Roybal Center, etc. Once they have expressed their interest about participating in the study coordinator will begin the screening process of checking their eligibility for the study. This will include verifying that they are a primary care partner of someone with DLB or PDD, did not participate in Aim 1, are willing and able to provide clear and concise consent, etc. In addition, the screening will also utilize the already established inclusion/exclusion criterions. After the eligibility criteria is met and their consent has been obtained, all subjects will be asked to provide contact/demographic information about themselves and begin the study procedures.

The project study coordinator will complete a thorough review of the study procedures and information with potential study subjects prior to obtaining consent. Potential study subjects will have an opportunity to ask questions and have their questions answered to their satisfaction prior to giving consent. The process of reviewing the study information will be conducted in a manner to facilitate questions from potential study subjects. If the project study coordinator is unable to answer a question, an investigator will be contacted. All questions from potential subjects will be answered prior to the project study coordinator obtaining consent. They will be reminded of the voluntary nature of study participation and the project study coordinator will explain the study, the voluntary nature of participation, the study's potential benefits and risks, and alternatives as needed for the subject. The study coordinator will also explain to the potential subject that even if they decide to drop out of the study, we will still use any data that we previously gathered, up to the point in which they decide to discontinue. An explanation of risks will include information that questions asked may cause subjects to feel uncomfortable or upset. They will be informed that they may withdraw from the study at any time for any reason without negative consequences to them. They will also be notified that all of their rights will be protected.

We plan to obtain documentation of consent for this Aim via e-consenting. Subjects will receive the form via email as a survey through REDCap. As a result of this, the mechanism of authorization will be via the electronic device they decide to use to fill out the e-consent form. To verify that the individual signing the consent form is the subject, there will be a verification code. This verification code will be the last 4 digits of the phone number they provide us with. Once received they can either go over the form on their own, over the phone with the help of the study coordinator, or over zoom with the study coordinator (if requested by the subject). A confirmation email is supposed to be sent to all respondents that have completed the survey, but because your email address is not on file, the confirmation email cannot be sent automatically. If you wish to receive it, you must provide your email address to the study coordinator. There will be a signature section at the end of the document which will confirm the subject's participation in the study. This will be an e-signature which will document that the subject understands the study, their procedures for the study, and that they consent to participate in it. Moreover, once the first 20 individuals have expressed interest and are consented into the study then they will be randomized as 10 intervention, 10 waitlist control. This will continue to be the recruitment/consent process until our recruitment goal of 60 subjects is met. We plan to administer this consent process via e-consent.

8. STUDY PROCEDURES (AIM 1)

Aim 1: Adapt the Life Enhancing Activities for Family Caregivers intervention to an online group intervention integrating social skills and connections. We will conduct these individual interviews with up to 20 care partners to adapt the LEAF course materials to a group setting. Also, we plan to incorporate social connections and skills (Social-LEAF) with these materials. We are looking for a max of 20 subjects to take part in this. We will be scheduling these potential subjects in a 6 week window based on their availability. Depending on the timing, there may be multiple individual interviews conducted in one day. Once they agree to take part in this portion of the study, subjects will join the interview and be exposed to the intervention (this will be completely virtual, and interviews will take place via the Zoom application). We will provide them the main basis of each element of the intervention during the interview, then go through the guide to see what kind of feedback we receive, Landmark Associates will be utilized to transcribe these interviews to help the study team further develop the intervention for Aim 2. Those who have participated in Aim 1 and aid in the adaptation of this intervention will be automatically ineligible for Aim 2.

- Aim 1 Procedures: The adaptation and tailoring process will consist of individual interviews, feedback, and consultation with the study team which some members have experience with supporting individuals who are dementia care partners. Explanation of the implementation of these interviews is above, and will be further outlined in sections below. As a first step, our core team will review the LEAF intervention, the LEAF-2 modifications (study in progress: R01AG058613) and the Positive Emotion Orientation for Nurturing Your Relationships intervention (PEONY: R01AA024065) to create the first draft of the Social-LEAF training manual

and guide. We will draw on these other interventions to deliver the CORE aspects of LEAF in a group context and to integrate social examples, skills, and positive social outcomes. We will then begin recruitment/enrollment for individuals who are interested, mainly through support groups and the Parkinson's Foundation. Individuals who enroll will be asked to provide basic contact information as part of their enrollment into the study, so that we are able to schedule them for the interview. During the interview subjects will receive a brief introduction to the intervention and its core components by the interviewer, who is a part of the study. The interviewer will then go through the interview guide and ask subjects questions about the intervention and acquire feedback from them. The interview will be recorded and later transcribed by Landmark Associates for our study team to review. Notably, Co-investigator Dr. Moskowitz (consultant and originator of LEAF, LEAF-2, and PEONY) has adapted her interventions to multiple populations and contexts using the procedures described below, including to a group intervention for men infected with HIV (PEONY). Dr. Moskowitz's main role within this study is to provide her own feedback and consultation on how the intervention should be provided to subjects. She has years of experience with these interventions and modifying them, so she will play an integral role in the finalization of the intervention for Aim 2. She will have access to the de-identified data of the subjects but she will not be directly interacting with them. Moreover, she will also play a part in quality assurance and making sure study procedures are being conducted properly for Aim 2. Additionally, Table 2 outlines the core components of the virtual 6-week LEAF intervention and how they may be adapted to social skills and content. Group adaptations would include the use of facilitated group discussions, role play, dyad exercises, and encouragement to connect between facilitated sessions.

- Outcomes will be the data/feedback we receive from the individual interviews (the materials for the adapted LEAF program, see **Study Procedures** below). Subsequent to this, after all the interviews have been conducted the main study team will get together to review and finalize the intervention in preparation for Aim 2. The research study coordinator will submit any RSRB modifications needed if anything within the intervention is changed subsequent to study approval.

Table 2. Current LEAF Content and Potential Adaptations for Social-LEAF

	Weekly Focus	Potential Adaptations
Week 1	Noticing Positive Events	Noticing the positive impact of social events both large (family visit) and small (email or card); Develop plans to build on social intentions
Week 2	Mindfulness	Learn to balance self-awareness and self-compassion with attentive listening and mindful connection
Week 3	Positive Reappraisals	Recognize role of negative attributions in disrupting social connections; Consider ways to share positive reappraisals of stressful events
Week 4	Strength and Goals	Recognizing social strengths (e.g., good listener) and positive attributes (e.g., sense of humor)
Week 5	Acts of Kindness	Appreciate the personal and relational benefits of both performing small acts of kindness and in receiving them

Week 6	Sustainment	Subjects develop concrete plans to continue to practice Social-LEAF skills including with members of their social network

9. STUDY PROCEDURES (AIM 2)

Aim 2: The goal of this aim is to assess the acceptability, appropriateness, feasibility, and efficacy of Social-LEAF. We will conduct a pilot randomized controlled trial of the Social-LEAF intervention in 60 subjects (30 intervention; 30 waitlist control) and use mixed methods to assess feasibility, acceptability and efficacy.

- Aim 2 Procedures: Subjects will complete six, weekly, 90 minute group sessions of the Social-LEAF intervention. Subjects enrolled in the study will be randomly assigned into either an immediate intervention group or a waitlist control (receives intervention after 6 weeks) by a computer program. Subjects will know which arm they will be in after enrollment in the study. The intervention will be delivered completely online. We ask that subjects find a nice and quiet area in which there is minimal distractions to conduct these visits. Subject privacy is very important to us. Subjects will be asked to complete a daily emotion check-in (5 minutes) during the 6-week course period. This will be delivered to them via Redcap as a survey as well. Prior to beginning the Social-LEAF course, they will receive a computer tablet to use for the study, if they express the need for it. Subjects will also be asked to complete our online outcome measures at each data collection point (3 total) approximately every 6 weeks (baseline, week 6, and week 12) after you are officially enrolled in the study. The total time to complete these activities in one day is approximately 2 hours and 15 minutes. Please refer to Table 4 for a list of these measures. Furthermore, if the study research coordinator sees anything concerning (I.e., signs of abuse, self-harm, etc.) during the duration of a research visit, then there are measures in place to address this. These measures include contacting the PI and chaplain immediately, relaying these concerns, and gathering as much information as possible before taking action towards this concern. There will be 3 groups of 10 (on average; this number may range from 5-15 depending on randomization, recruitment and retention) that will be in each group (intervention or control). Each group of subjects will go through the study procedure together. Data from subjects in all groups will be collected at baseline, week 6, and week 12. Data collection will happen via zoom/via Redcap survey sent to them by the email subjects initially provide the coordinator with. The waitlist control subjects will start the intervention at week 6 but still complete the measures for data collection at baseline, week 6 and week 12. Table 3 displays the timeline in which the study procedures for Aim 2 will take place. Planned deliverables from this aim will include a final intervention manual, a manuscript on the pilot intervention, and pilot data suitable to pursuing future grant opportunities.
- Quantitative Survey Outcome Measures: Our primary outcome measure is the PROMIS Positive Affect Scale. We will also be assessing the Positive Aspects of Caregiving scale (positive consequences of caregiving)[10] and other measures of caregiver distress and wellbeing (see Table 4). These measures will be administered at each data collection point mainly via Redcap as a survey, and/or via the study

coordinator administering it as required by the scale. The health history data will be collected when the subject initially consents, and updated as the study progresses. Altogether, the duration to complete these measures altogether is roughly 2 hours and 15 minutes.

Table 3. Aim 2 Procedures Timeline

	Intervention	**Waitlist Control**
Baseline	Data collection point, Start online LEAF procedures	Data collection point
Week 6	Data collection point	Data collection point, Start online LEAF procedures
Week 12	Data collection point (maintenance)	Data collection point

Table 4. Outcome measures

Demographics (Baseline)	UCLA Loneliness, short form
Modified Barthel Index (Baseline)	Perceived Stress Scale (PSS-10)
FAST (Baseline)	Positive Aspects of Caregiver scale
PROMIS social isolation	Berkman-Syme Social network
PROMIS satisfaction w/ roles and activities	Modified Caregiver Strain Index
PROMIS depression	SF-14
PROMIS anxiety	Montgomery Borgata Caregiver Burden Scale
PROMIS Positive Affect Scale	UCLA Loneliness, version 3
NPI-Q	Differential emotions scale

- Aim 2 Feasibility and Efficacy Outcomes: We will utilize the RE-AIM framework to assess feasibility including: % of subjects approached who join the study **(Reach)**; change in survey results **(Efficacy)**; % of subjects who complete all intervention activities **(Adoption)**; fidelity of facilitators to the manual as written **(Implementation)**; and % of subjects who continue to engage in these skills 6-weeks following the intervention **(Maintenance)**.
- Aim 2 Interviews and Value Proposition Design: We will conduct a semi-structured end of study interview with select subjects at the completion of the study to understand their perspectives on whether the intervention was beneficial, how it impacted their personal and social lives, and how it was received by others in their social network. Additionally, we would like to receive feedback on what specifically worked for them and what areas they would personally modify. To understand opportunities for any further improvements we will follow customer discovery and value proposition design guidance and materials from Osterwalder et al.[11] This framework allows us to gain greater depth into the perceived "jobs, pains, and gains, of daily care partner and features of the intervention and related social support that serve as "gain creators and pain relievers." Care partners will undergo a single, brief and focused interview at the end of the study to see whether and where they noticed any changes in social interactions with the primary subject and whether they have suggestions for further improvement.
- Analysis: Our primary analyses of surveys and data will be descriptive with particular attention paid to feasibility and to which scales appear most and least responsive to

the intervention. Secondary quantitative analyses will explore mechanisms and qualitative analyses will be used to gain further insights into how Social-Leaf benefits care partners, what outcomes are most meaningful and whether further adaptations are needed.

Demographic data will be obtained by the URMC project study coordinator after study subjects have provided their consent to participate. The information will be provided by subjects via Zoom and/or REDCap survey sent to their email. The demographic information will be documented in the University of Rochester's REDCap system.

End of study interview will be conducted by the URMC project study coordinator who is trained in interview techniques. Subjects will be scheduled for a video interview via Zoom based on their choice and convenience. Interviews will be conducted at a time convenient to the subject, will be audio-recorded using Zoom connected to a URMC-approved HIPPA-compliant account. Interviews with the research coordinator will typically last approximately 30-45 minutes.

Interview questions will focus on recognizing that people have the capacity to experience positive emotion even in the midst of distressing circumstances, identifying recent positive events and things to be grateful for, having a basic understanding of gratitude and the potential benefits it might have, etc.

The interview will be audio recorded so that the full conversation can be transcribed for later analysis, and subjects will be informed of this before the discussion begins. No identifying information (for example, subject names, or other personal details shared during the discussion) will be included in the transcript.

Return of Research Results

As part of this study, we may learn information relevant to subject. If this happens, we will provide them information that would be relevant once the study is complete. Subjects will be given the option at the end of this consent to decide if they would like to receive these relevant results. For the interpretation of these results, we strongly recommend subjects contact their primary care physician.

Some things subjects should know about results:

- Sometimes the meaning of the results will be uncertain. It is important to know that our understanding of health is changing quickly, and in many cases, we may not know for sure what the results mean for a subject's future health.
- Any results we return to subjects will first be verified by the PI.

10. AUDIO/VIDEO RECORDINGS

A URMC-approved HIPPA-compliant zoom account will be used to conduct the recording of the interviews. Recordings of interviews will be deleted from the recording

devices once the recordings are transferred from the recording devices to Landmark Associates for transcription. All recordings will be transcribed and the transcription will be kept for three years following the completion of the study and then destroyed. Subjects can request to have these recordings destroyed at any time. Interview recordings will be transcribed by Landmark Associates, a transcription company that has been approved and vetted by the University of Rochester IT Security. All files transmitted or stored in their system are protected by multiple layers of encryption through Amazon's S3-managed encryption keys (SSE-S3). With SSE, every file is encrypted with a unique key, which is also encrypted by a separate master key which rotates regularly. The encrypted data, encryption keys and master keys are stored and secured on separate hosts for additional layers of protection. In addition, Landmark internally implements two-factor authentication for administrative users, which adds an additional safeguard in the login process. Login attempts that do not have the valid credentials from both sources are not granted access to the system. In addition, Landmark implements IP restrictions, preventing those who try to login to their system outside the designated IP address to gain access. Each employee, executive staff member and contractor of Landmark is required to sign a non-disclosure and confidentiality agreement, and follow Landmark's security policies.

10. RISKS TO SUBJECTS

For the majority of study activities (which include the qualitative/quantitative measures, the intervention, and the interview) the primary risk is mild reactions of distress or fatigue or is invasion of privacy, and/or breach of confidentiality (if safety issues are detected). It is possible that conversations around certain conditions, telehealth, or support needs could cause distress or anxiety. The URMC project study coordinator is trained to recognize potential signs of fatigue and distress among subjects and is experienced in coordinating the interviews. During the course of the semi-structured interviews, the researcher will listen for signs of fatigue and will offer subjects a break from the interview, or provide them with the option to complete the interview over several sessions if needed. If subjects express or demonstrate signs of distress, they will have the option to decline answering a question. There is the possible risk of unauthorized release of interviews that could result in release of private information. All and every effort will be made to minimize any breach of data and ensure that all data are de-identified. There is potential risk of signs of depression and suicidal ideation. If the study team finds a subject exhibiting these characteristics, they will address this immediately by contacting the chaplain. The research study coordinator will ascertain their risk by their responses to questionnaires and their overall discretion on how the subject is interacting with them. They will contact the PI and /or chaplain for immediate assistance/guidance to develop a plan to address the issue. Lastly, if the study team learns that you or someone with whom you are involved is in danger or potential harm, such as elder abuse they will need to inform, as required by New York State law, the appropriate agencies.

11. POTENTIAL RISK TO SUBJECTS

Fatigue, stress, topics that may be saddening, conversation about these topics, invasion of privacy, etc.

12. POTENTIAL BENEFITS TO SUBJECTS

There are no anticipated benefits.

13. COSTS FOR PARTICIPATION

None anticipated

14. PAYMENT FOR PARTICIPATION

Subjects will receive $25 for successfully completing the individual interview for Aim 1. For Aim 2, they will receive $25 for the completion of each data collection point associated with the study. This includes baseline, week 6, and week 12, for a total of $75. Individuals who express interest and are chosen to do the post-intervention interview will receive $25 as well, which can will total their compensation to $100.

15. SUBJECT WITHDRAWALS

Subjects are free to withdraw at any time without negative consequences. Subjects may also refuse to answer any individual questions. If a subject voluntarily withdraws from the study, we will attempt to the note the reason if provided by the subject. We will use the data already collected up until the point in which the subject decides to voluntarily withdraw from the study. In the event of the latter, subjects who withdraw from the study will be replaced.

16. PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA

We are requesting altering HIPAA authorization so as to obtain permission during the verbal consent process to gather subjects' demographic data.

- Elements of authorization are being altered
- Without subjects' phone, email, and home address the study data collection and the mailed check for participation cannot be completed. Other demographic data such as race/ethnicity are important to answering the study research questions as they will facilitate an understanding of the challenges, barriers, and supports experienced by different subjects.
- The demographic data being gathered are no more than minimal risk to the privacy of the individuals
- All identifying information will be maintained on the REDCap system at the University of Rochester and printed copies of subject's names, email, and home addresses will be held by the URMC project study coordinator in a locked cabinet in her office at the University of Rochester and on an encrypted University of Rochester computer. All identifying information will be destroyed three years after the completion of the study.
- PHI will not be reused or disclosed to any other person or entity except (i) as required by law, (ii) for authorized oversight of the research study, or (iii) for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule.

In order to protect the confidentiality of subject information, we will take a number of precautions. All data will be securely stored and maintained according to the regulations of privacy stipulated by the University of Rochester. All data will be held by the URMC

project study coordinator in a locked cabinet in her office at the University of Rochester and on an encrypted University of Rochester computer. Audio recordings of semi-structured interviews will be transcribed and then kept three years following the completion of the study. Demographic information and de-identified transcripts will be stored on an encrypted, password protected computer and will be accessible only to the study PI and study team members. Back-ups of all study files will be made daily to allow for recovery of data due to disk failure. Confidentiality will be further maintained by the storage of "hard copy" data in locked files in a locked office. Only the research team and approved study personnel will have access to the data. All data reported in presentations or publications will be de-identified and will report only cumulative data or descriptions certain to maintain subjects' anonymity.

15. DATA / SAMPLE STORAGE FOR FUTURE USE

N/A

16. DATA AND SAFETY MONITORING PLAN

N/A

17. DATA ANALYSIS PLAN

Qualitative analyses (Aim 1) will use Atlas.ti software for coding and an inductive approach.[11] We will iteratively modify materials alongside interviews and will plan to pilot our group approach in single sessions of several modules to troubleshoot materials before finalizing pilot materials for Aim 2. For qualitative analyses in Aim 2, to understand opportunities for any further improvements we will follow customer discovery and value proposition design guidance and materials from Osterwalder et al.[12]

For Quantitative analyses (Aim 2), our primary analyses of surveys and data will be primarily descriptive with particular attention paid to feasibility and to which scales appear most and least responsive to the intervention. Secondary quantitative analyses will explore mechanisms and qualitative analyses will be used to gain further insights into how Social-Leaf benefits care partners, what outcomes are most meaningful and whether further adaptations are needed. With 60 subjects we will be able to detect large between-group differences (0.7 SD/mean) and modest pre/post differences (0.5 SD/mean), which fall within the range of the original LEAF results.[8]

18. REFERENCES

1) Creutzfeldt CJ, Kluger B, Kelly AG, et al. Neuropalliative care: Priorities to move the field forward. Neurology 2018;91:217-226
2) Boersma I, Jones J, Carter J, et al. Parkinson disease patients' perspectives on palliative care needs: What are they telling us? Neurol Clin Pract 2016;6:209-219.
3) Boersma I, Jones J, Coughlan C, et al. Palliative Care and Parkinson's Disease: Caregiver Perspectives. J Palliat Med 2017;20:930-938.

4) Kluger BM, Shattuck J, Berk J, et al. Defining Palliative Care Needs in Parkinson's Disease. Mov Disord Clin Pract 2019;6:125-131.
5) Kluger BM, Miyasaki J, Katz M, et al. Comparison of Integrated Outpatient Palliative Care With Standard Care in Patients With Parkinson Disease and Related Disorders: A Randomized Clinical Trial. JAMA Neurol 2020.
6) Kluger BM, Vaughan CL, Robinson MT, Creutzfeldt C, Subramanian I, Holloway RG. Neuropalliative care essentials for the COVID-19 crisis. Neurology 2020.
7) Beebe, J. *Rapid Qualitative Inquiry: A Field Guide to Team-Based Assessment*. Second Edition. Rowman & Littlefield, Lanham, Maryland. 2014
8) Neal JW, Neal ZP, VanDyke E, Kornbluh M. Expediting the analysis of qualitative data in evaluation: A procedure for the rapid identification of themes from audio recordings (RITA). American Journal of Evaluation. 2015;36:118-132.
9) Norton SA, Ladwig S, Caprio TV, Quill TE, Temkin-Greener H. Staff Experiences Forming and Sustaining Palliative Care Teams in Nursing Homes. Gerontologist. 2018;58(4):e218-e225.
10) Boerner K, Schulz R, Horowitz A. Positive aspects of caregiving and adaptation to bereavement. Psychol Aging. 2004;19(4):668-675.
11) Osterwalder A, Pigneur Y, Bernarda G, Smith A. Value proposition design: How to create products and services customers want. John Wiley & Sons; 2014