Title: Social-LEAF Life Enhancing Activities for Caregivers

NCT05274074

Informed Consent Form
Date: 1/31/2023

Improving Dementia with Lewy Bodies Care Partner Outcomes through Positive Connections

Principal Investigator: Dr. Benzi Kluger

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you are a primary care partner of someone with Dementia with Lewy Bodies (DLB) or Parkinson's Disease Dementia (PDD).
- This is a clinical trial of a behavioral intervention; information about this study will be available on clinicaltrials.gov. NCT #: 05274074
- The purpose of this study is to use the Life Enhancing Activities for Family Caregivers (LEAF) intervention by adapting it to a group setting and tying in these skills to social connections (Social-LEAF). LEAF is an online intervention that helps care partners increase their levels of positive emotions. 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.
- Your participation in this study will last about 12 weeks. You will be invited to complete an end-of-study interview that will take place after the 12 weeks).
- Whether or not you decide to participate in this study will not influence the care that your family member with dementia receives from their health care providers.
- There are risks from participating in research.
    - The most common risk related to this study are fatigue and distress.
    - The most serious risks related to this study are some questions may make you feel emotional, invasion of privacy, and breach of confidentiality.
- We are testing this intervention to see if it helps care partners.
- Your participation is completely voluntary, and you may skip questions you do not wish to answer. The Social-LEAF program is not therapy and does not offer

counseling or mental health services. This study does not replace seeing your health provider and/or therapist, nor does it replace taking any medication. Please follow the recommendations of your health provider.

Purpose of Study

The purpose of this study is to further the work of utilizing 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 learn whether social networks can be used as a tool for reinforcing the positive life skills of the intervention. Also, we want to study whether the skills learned from participating in Social-LEAF will improve social networks, increase satisfaction in social situations, and boost motivation to reach out to others, thus combatting social isolation.

Description of Study Procedures

The Social-LEAF course consists of 6 skills delivered online, through video-conferencing ("video sessions") with a trained facilitator, to help manage your mood and cope with the stressors of caregiving. If you decide to participate in this study, you will be assigned by chance (like flipping a coin) to one of two groups: either the immediate intervention group, or a waitlist control group. There is an equal chance that you will be assigned to either group. The immediate intervention group will start the Social-LEAF program right away (within 1 week of being assigned to this group). The waitlist control group will start the intervention 6 weeks later. If you decide to take part in this study, you will be asked to complete the following activities:

Social-LEAF Intervention (6 weeks):

- Six, weekly, 90 minute group sessions of the Social-LEAF intervention. During the sessions we will discuss 5 core components which are Noticing Positive Events, Mindfulness, Positive Reappraisals, Strength and Goals, Acts of Kindness, and Sustainment. You will participate in the sessions along with about 9 other individuals (group size may range from 5-15)

- Daily practice activities (approx. 5 mins per day) that will include up to 25 questions that ask about your mood, stress level, and overall well-being in the past 24 hours.

Questionnaires (3 times, approx. 2 hours):

Regardless of which group you are assigned to, you will also be asked to complete study questionnaires at baseline (when you enroll in the study), at week 6, and again at week 12. These measures will be administered at each data collection point mainly via Redcap (an online tool to which you will be given access) as a survey, and/or via the study coordinator administering it as required by the scale. Data collection will happen via zoom/via survey sent to you by the email you initially provided the coordinator with.

The questionnaires will ask about your experiences as a care partner, your emotions toward it, and how you feel overall. It will take about 2 hours to complete. Your privacy is very important to us. The intervention will be delivered completely online. We ask that you find a nice and quiet area in which there is minimal distractions to conduct these sessions If the study research coordinator sees anything concerning during the duration of the 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.

The quantitative surveys are by the Star CORE Battery Assessments to cover different domains such as how you sleep, how you are coping with being a care partner, your depression scale, etc.

End-of-Study Interview (approx. 30-45 mins.):

At the end of your participation in the intervention, you will be invited by the study team to take part in a one-time interview. You will be asked about your experience in the study, your opinion on the intervention, and ways in which we can improve. It will last about 30-45 minutes. We will use Zoom to record your voice during the interview. There will be a question at the end of this document requesting your consent to being recorded. The recording will be safely sent to Landmark Associates to be transcribed and sent back to the study team to review.

Lastly, we ask that you find a nice and quiet area in which there is minimal distractions to conduct these surveys and sessions. Your privacy is very important to us. If the study research coordinator sees anything concerning (I.e., signs of abuse, self-harm, etc.) during the duration of the session, 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. Moreover, there will be 3 groups of 10 subjects that will be in each condition (intervention/waitlist control). Data from subjects in all groups will be collected at baseline, week 6, and week 12.

Number of Subjects

We estimate up to 60 people will take part in this study (30 intervention group, 30 waitlist control group).

Risks of Participation

During the intervention or when completing questionnaires you might experience anxiety, stress, or emotional discomfort when discussing topics or answering questions about your caregiving responsibilities, stress level or your care recipient's diagnosis. The most common risk related to this study is fatigue. You may also feel fatigue from participating in the group intervention sessions or completing the questionnaires. If there

is ever a case where the questions are causing any signs of discomfort, emotional distress, or fatigue you can take a break from answering them and coming back at a later time to complete it. If there is continued discomfort you may skip the questions causing this, the study coordinator will make note of this via REDCap comments. There is potential risk of signs of depression and suicidal ideation. The study team will contact the chaplain or study investigators to quickly assess and handle the matter.

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, we may need to report this to the proper agencies to handle this matter.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

Risks related to email: You have the option to receive communications about this study via email and/or text messaging, by indicating your consent at the end of this form. Email communications between you and the study team may be filed in your research record.

Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email.

Benefits of Participation

You might not benefit from being in this research study. It is possible that participating in the Social-LEAF groups might lead to less care partner pressure and a more positive outlook on being a care partner. However, this is not guaranteed.

Payments

You will be paid $25 after completing each set of questionnaires at baseline, week 6, and week 12 for up to $75. If you take part in the end-of-study interview, you will be paid another $25 for a total of $100. You will not be paid for interviews/study procedures that you do not complete. We will send a check to you after you complete the questionnaires and interview at each of these time points.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will collect de-identifiable information and be utilizing Redcap to securely store the data collected. Sometimes, however, researchers need to

share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Results of quantitative measure

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- Dr. Judith Moskowitz – one of the principal investigators from Northwestern University who has years of experience with the utilization and modification of the LEAF intervention.

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

How long will this permission be valid?

This permission will last up to 3 years after study completion.

May I cancel my permission to use and disclose information?

Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?

Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

No. There is a risk that your information will be given to others without your permission.

In order to collect study information, we have to get your permission to use and give out your demographic data. We will collect your demographic data at the first data collection point after you have consented.

Your permission to use this information for this study will not expire unless you tell us you want to cancel it. You do not have to provide us with this information if you do not wish too. This will not affect your participation in the study and you will still be able to conduct study procedures. We will keep the information we collect about you indefinitely.

This study will be conducted with the help of individuals outside the University of Rochester, which we will be sharing select data with. These contributors include:

Future Use of Information/Samples

Your information might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your information is used or distributed. You will be given the option at the end of this consent form to decide if you would like your information used for future research.

Early Termination

If you miss your scheduled visit after being contacted multiple times by the study coordinator, you may be withdrawn from the study by the investigator. You may also be withdrawn from the study if the study coordinator is not able get in contact with you after 3-4 attempts.

New Study Information

If we discover any new information that might make you change your mind about continuing in the study, we will inform you in a timely manner.

Sponsor Support

This study and the University of Rochester is receiving payment from the STAR Constellation Pilot Award by the Roybal Center for conducting this research study.

*Return of Research Results

As part of this study, we may learn information relevant to your health, such as being depressed and/or suicidal ideations. If this happens, we will provide you information that would be relevant once the study is complete, or in more serious matter, at the time it becomes relevant to the study team. You will be given the option at the end of this consent to decide if you would like to receive these relevant results. For the interpretation of these results, we strongly recommend to contact your primary care physician.

Some things you 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 your future health.
- Any results we return to you will first be verified by the PI.

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Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Dr. Benzi Kluger at (585) 275-4259.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;

- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner. Moreover, we will still use any data that we previously gathered, up to the point in which they decide to discontinue.

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CONSENT TO BEING AUDIO-RECORDED

(*Answering no will not affect your participation in the study, you just will not be chosen to do the end-of-study interview.)

May someone from the study team, utilize an audio recording device to record you for the end of study interview?

Yes No

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

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Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date