INFORMED CONSENT FORM

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NCT04837937

Consent to Participate in Research

Title of Research Study: Negotiation Training to Optimize Caregiver Communication in Alzheimer's Disease

Principal Investigator: Lee A. Lindquist, MD, MPH, MBA

Supported By: This research is supported by the NIH National Institute on Aging.

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is explained later on in this form.

- The purpose of this study is to design a Negotiation and Dispute Resolution (NDR) training intervention to improve communication and address resolution of conflicts that family caregivers of patients with Alzheimer's Disease frequently experience.
- You will be asked to complete a series of NDR activities online. You will also be asked to complete an initial online survey and three follow-up online surveys.
- We expect that you will be in this research study for approximately 3 months and your participation may take up to 2.5 hours across that entire time period.
- The primary potential risk of participation is that you may face emotional discomfort in answering questions and completing activities related to conflicts/arguments that you may have experienced in helping to care for an older adult.
- The main benefit of being in this study is that you will be exposed to NDR exercises/information and as a result, may gain useful knowledge. You may also experience an indirect benefit of being involved in research that may lead to meaningful changes in howwe can best support caregivers of people with Alzheimer's Disease/memory loss.

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 Web site at any time.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because:

- You are at least 21 years old;
- Speak and read English;
- You provide caregiver support to an adult over the age of 65 with cognitive loss and/or Alzheimer's Disease and you are involved in decision-making related to their healthcare and support;
- You provide that caregiver support for at least one hour per week;
- You have access to a desktop or laptop computer with internet or a mobile device (smartphone, tablet) with internet to complete the study activities; and
- You have a valid email address (or willingness to create one for study purposes).

How many people will be in this study?

We expect about 150 people will be in this research study.

What should I know about participating in a research study?

- Someone will explain the research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- You do not have to answer any question you do not want to answer.

What happens if I say, "Yes, I want to be in this research"?

If you choose to participate in this study, you will be asked to complete the following activities over the course of a 3-month period. All activities will be completed online.

Activity	Description	Duration
Baseline Survey [Survey 1]:	Initial online study survey including questions about yourself, negotiation knowledge, etc. Participants will have 7 days to submit their completed survey.	Up to 35 minutes
Assigned NDR Exercises [Activity 1]**	Series of online negotiation exercises. Participants will have 14 days to complete **all** of their assigned negotiation exercises.	Up to 1 hour
Post-Intervention* Survey [Survey 2]	Survey including questions about yourself, negotiation exercise feedback, etc. To be completed after Activity 1. Participants will have 7 days to submit their completed survey.	Up to 25 minutes
1-Month Follow-Up Survey [Survey 3]	Survey approximately 1-month after completion of Survey 2. Participants are expected to submit their complete Survey 3 within ±14 days of being sent the survey link by the study team.	Up to 25 minutes
3-Month Follow-Up Survey [Survey 4]	Survey approximately 3-months after completion of Survey 2. Participants are expected to submit their complete Survey 4 within ±14 days of being sent the survey link by the study team. This is the final study survey.	Up to 30 minutes

**The group of NDR exercises you will be assigned to complete will be chosen by chance, like flipping a coin. Neither you nor the study team will choose which study group you are assigned to. You will have a 1 in 8 chance of being assigned to any given group.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include being exposed to NDR exercises/interventions where you may gain useful knowledge as a result. You may also experience the indirect benefit of being involved in research that may lead to meaningful changes in how we can best support caregivers of people with Alzheimer's Disease, cognitive loss, and/or dementia.

Is there any way being in this study could be bad for me?

There is minimal risk to study participation. While we work to keep your study information secured and confidential, there is a risk of loss of confidentiality. A possible risk for any research is that confidentiality could be compromised – that is, that people outside the study might get hold of confidential study information. We will do everything we can to minimize this risk, as described in more detail later in this form.

Psychological risks: Some participants may face emotional discomfort in completing study surveys and completing NDR activities which may involve answering questions and thinking about the conflicts/arguments they may have experienced/are currently experiencing in caring for an older adult with cognitive loss.

A possible risk for any research is that confidentiality could be compromised – that is, that people outside the study might get hold of confidential study information. We will do everything we can to minimize this risk, as described in more detail later in this form.

What happens if I do not want to be in this research, or I change my mind later?

Participation in research is voluntary. You can decide to participate or not to participate. If you do not want to be in this study or withdraw from the study at any point, your decision will not affect your relationship and/or healthcare services with Northwestern University/Northwestern Memorial Healthcare.

You can leave the research at any time and it will not be held against you. If you decide to withdraw from this study, the researchers will ask you if information collected from you can be used.

How will the researchers protect my information?

We have various procedures in place to keep your information secure and confidential. For example, we use encrypted computers to collect and store your study data. The research database is password protected and accessible only to the research team and the Institutional Review Board. We also store any identifiable information, such as your name, separately from the rest of the research data. Participants are assigned a study ID to avoid using any information that may identify you.

Certificate of Confidentiality:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may

identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

Identifiable information that could still be disclosed beyond the research team: The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Who will have access to the information collected during this research study?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy.

There are reasons why information about you may be used or seen by other people beyond the research team during or after this study. Examples include:

- University officials, government officials, study funders, auditors, and the Institutional Review Board may need access to the study information to make sure the study is done in a safe and appropriate manner.

How might the information collected in this study be shared in the future?

We will keep the information we collect about you during this research study for study recordkeeping. Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information we collect from you.

De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for research. We will remove or code any personal information that could directly identify you before the study data are shared. Despite these measures, we cannot guarantee the anonymity of your personal data.

The results of this study could be shared in articles and presentations but will not include any information that identifies you.

Will I be paid or given anything for taking part in this study?

You will receive up to $500 in virtual Visa gift cards for your participation in this study. You will only receive compensation for the activities that you complete. You will still be allowed to participate in

the study even if you do not complete all the study activities. Activities and the corresponding compensation upon completion are explained below:

Activity, by time-point	Estimated Duration	Virtual Visa Gift Card Compensation Amount
Baseline: Survey 1	Up to 35 minutes	$25
Immediate-Post Intervention*: Survey 2	Up to 60 minutes	$300
1-Month Post Intervention: Survey 3	Up to 25 minutes	$75
3-Months Post Intervention: Survey 4	Up to 30 minutes	$100
TOTAL	**2.5 hours**	**$500**

*Includes completion of Study Intervention - Assigned NDR Exercises in addition to Survey 2

Who can I talk to?

If you have questions, concerns, or complaints, you can contact the Principal Investigator Lee A. Lindquist at (312) 503-5558 or email at LAL425@northwestern.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB") – an IRB is a committee that protects the rights of people who participate in research studies. You may contact the IRB by phone at (312) 503-9338 or by email at irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Electronic Consent

Do you wish to participate? Record participant's response: Yes No

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may keep my contact information in order to contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator.

Your signature documents your permission to take part in this research.

_____ _____

Electronic Signature of participant ***Date***

_____

Type name of participant

_____ _____

Signature of person obtaining consent ***Date***

_____

Printed name of person obtaining consent