STUDY PROTOCOL

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STUDY TITLE: Negotiation Training to Optimize Caregiver Communication in Alzheimer's Disease

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RELATED STUDIES:

N/A

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	Institution	Human Research Assessment *** (e.g., Non-Exempt Human Research, Exempt Human Research, Not Human Research, etc.)
Prime Award Recipient*	Northwestern University Feinberg School of Medicine	Human Research
Sub-Award Recipients**	N/A	N/A

1.0 Purpose and rationale of the study:

The purpose of this study is to design a Negotiation and Dispute Resolution training intervention to improve communication and address resolution of conflicts that family caregivers of patients with Alzheimer's Disease (AD) or memory loss frequently experience.

Specific aims:

Aim 1: Employ a caregiver (user)-centered design approach to modify and tailor negotiations and dispute resolution (NDR) training intervention to support communication skills of family caregivers of adults with AD.

Aim 2: Utilizing Multiphase Optimization Strategy (MOST), conduct a randomized trial of the NDR intervention that targets better communication between caregivers and health teams, using a 2^{-3} full factorial design, to (2a) determine the feasibility of delivering the intervention, and (2b) derive estimates of the effect of 3 intervention components on changes in patient-centered outcomes at post-intervention and follow-up.

Exploratory Aim 3: Explore if intervention components (lectures/exercises) interact to change communication between caregivers and health care teams at post-intervention and follow-up.

2.0 Enrollment Criteria (who can be in your study and who would not be eligible to participate in your study):

No subjects will be excluded on the basis of race or ethnicity.

In **Aim 1**, participants will be eligible if they:

1. Are age 21 or older;
2. Speak and read English (NDR is currently not available in other languages);
3. Provide caregiving support (e.g. emotional, social, physical, task-related) to an older adult (>age 65) at least one hour per week;
4. Older adult for whom they provide support to has cognitive loss based on the results of the informant AD8 screening tool (AD8 score >2 to have cognitive loss);
5. Are involved in decision-making related to the healthcare and support of the older adult with cognitive loss; and
6. Have access and the ability to use a desktop or laptop computer with internet (the application is not currently mobile or tablet-friendly).

In **Aim 2**, participants will be eligible if they:

1. Are age 21 or older;
2. Speak and read English (NDR is currently not available in other languages);
3. Provide caregiving support (e.g. emotional, social, physical, task-related) to an older adult (>age 65) at least one hour per week;
4. Older adult for whom they provide support to has cognitive loss based on the results of the informant AD8 screening tool (AD8 score >2 to have cognitive loss);
5. Are involved in decision-making related to the healthcare and support of the older adult with cognitive loss;
6. Have access and the ability to use the internet to access the program (currently supported on mobile, tablet, laptop or desktop); and
7. Have a valid email address and/or willingness to create an email account for study purposes.

3.0 Sample Size:

Aim 1: We will recruit up to 15 family caregivers to participate in Aim 1. Data collected for Aim 1 will include both quantitative and qualitative data. Based on previous research it has been shown that 12-15 interviews are enough to reach thematic saturation in qualitative studies. Through our own experiences conducting qualitative studies, we anticipate reaching thematic saturation with this number.

Aim 2: We will recruit up to 150 family caregivers to participate. We will keep recruiting until we reach the target of 120 family caregivers who complete all the aim 2 activities, so we may recruit less than 150 participants. Proposed sample size is based off statistical power analysis which shows that n=120 will likely allow us to find

statistical significance if the studied effect(s) exist in the full population.

Recruitment and Screening Methods

Recruitment

Aim 1: We will recruit up to 15 family caregivers as study participants for Aim 1. We will recruit family caregivers through the Northwestern General Internal Medicine & Geriatrics Clinics as well as through our community partners. The study PI will present this study to healthcare providers at the Northwestern Medicine Geriatrics Clinic and ask them to pass along study information (recruitment flyer) to family caregivers that may be interested in the study. Potential subjects who are interested in learning more about the study will contact the Northwestern University research staff by phone or email. We will screen interested participants for eligibility over the telephone.

We are also collaborating with three community-based family caregivers as consultants in Florida, New York, and suburban Illinois. These partners will comprise the study's family caregiver advisory panel and will share this research study opportunity through word-of-mouth to family caregivers who may be interested in participating. They will distribute recruitment flyers containing study information. Potential subjects who are interested in learning more about the study will then contact the Northwestern University research staff by phone or email to learn more about the study and be screened for eligibility.

Aim 2: We will recruit up to 150 family caregivers as study participants for Aim 2. We will recruit family caregivers through the Northwestern General Internal Medicine & Geriatrics Clinics as well as through our community partners. The study PI will present this study to healthcare providers at the Northwestern Medicine Geriatrics Clinic and ask them to pass along study information (recruitment flyer) to family caregivers that may be interested in the study. Potential subjects who are interested in learning more about the study will contact the Northwestern University research staff by phone or email. We will screen interested participants for eligibility over the telephone.

Additionally, we will be utilizing ResearchMatch as a study recruitment tool. ResearchMatch, is a national health volunteer registry that was created by several academic institutions and supported by the U.S. National Institutes of Health as part of the Clinical Translational Science Award (CTSA) program. ResearchMatch has a large population of volunteers who have consented to be contacted by researchers about health studies for which they may be eligible.

We are also collaborating with three community-based family caregivers as consultants in Florida, New York, and suburban Illinois. These partners will comprise the study's family caregiver advisory panel and will share this research study opportunity through word-of-mouth to family caregivers who may be interested in participating. They will

distribute recruitment flyers containing study information. Social media will also be used to recruit potential subjects. Twitter and Facebook will be used to disperse study information to family caregivers nationally. Additionally, we are partnering with an Area Agency on Aging in Fort Wayne, IN which provides a variety of services to caregivers, and they will also help to recruit participants for Aim 2.

Potential subjects who are interested in learning more about the study will then contact the Northwestern University research staff by phone or email to learn more about the study and be screened for eligibility.

Screening for Eligibility

Aim 1: Interested participants will contact the Northwestern University research team to be screened for eligibility over the phone using the Aim 1 study inclusion criteria.

Data collected during the screening for eligibility for those study participants who are eligible and do participate in the study will be housed securely in the study screener data collection instrument on REDCap survey software. The questions asked during the study screener require no identifiers and will help us keep track of recruitment and screening status. We will discard screening data for people who are not eligible for the study or are eligible and decide not to participate, with the exception of demographic data we need to report for screening purposes.

Eligible study participants for Aim 1 of the study will provide electronic consent (e-consent) using REDCap to participate in the study. The Northwestern University research study coordinator will obtain e-consent for all enrolled study participants.

Aim 2: Interested participants will contact the Northwestern University research time by either emailing, clicking the ResearchMatch link which will generate an email, or calling the phone number listed on recruitment materials. The study-specific email is monitored by research study coordinators and the research project manager. The phone number directs the participant to the primary research study coordinator. Study team staff will take the interested participant's phone call and provide an overview of the study. If the participant reaches out via email, staff will send a message asking for a phone number to reach them to discuss the study.

If the participant is interested, and meets eligibility criteria, study staff will collect contact information (phone number, email address, mailing address) and a phone call will be set up where research staff will further explain the study in more detail, sign the electronic Informed Consent Form (participant will view eConsent while on the call), and upon consent, complete a baseline survey using the online REDCap survey platform.

NOTE: If participant has time to complete the e-consent after eligibility is determined, this can be done on the same day and does not necessitate a separate appointment.

Data collected during the screening for eligibility for those study participants who are eligible and do participate in the study will be housed securely in the study screener data collection instrument on REDCap survey software. The questions asked during the study screener require no identifiers and will help us keep track of recruitment and screening status.

4.0 Research Locations

Aim 1: The research will take place virtually, with study activities for Cycle 1 and Cycle 2 completed online using the Zoom Cloud Meetings (Zoom) video teleconferencing software program; Cycle 3 will involve an electronic REDCap survey and a semi-structured interview completed over the phone. Data collection will entail using the online REDCap survey platform and Zoom.

Aim 2: The research will take place virtually, with study screening taking place over the phone and study activities completed online via the study website, www.NegotiAge.com. Data collection will entail participants answering survey questions using the online REDCap survey platform.

We do not anticipate study participants being located outside of the United States for either study aim.

5.0 Multi-site Research (research that involves external collaborating institutions and individuals):

This study is only taking place at one site, Northwestern University, however it involves various independent consultants. Some consultants are community-based stakeholders who are not affiliated with any institutions, while other consultants are from collaborating institutions (University of Southern California and University of Central Florida). Community-based caregiver consultants will assist with developing dialogue and content for the negotiation cases, provide feedback to the research team on proposed study protocols, educational materials, and surveys, and will help disseminate our participant recruitment information. Our academic collaborators will help tailor the online negotiation platform for our study using our content/dialogue, collaborate with our web developer to integrate the online platforms, and assist in analyzing de-identified data. None of the external collaborators, community-based or academic, will enroll or consent participants into this study nor will they participate in any other human research activities as defined by the IRB.

6.0 International Research (where data collection will occur outside the United States and U.S. territories, including online activities): N/A

Please check the boxes for all applicable data collection procedures you plan to use:

☒One-on-one interviews
☐Focus Groups
☒Questionnaires/surveys
☐Analysis of secondary data (medical record data, educational records, government or private sector datasets, etc.)
☐Ethnographic observation
☐Physiological measurements (e.g., EEG, EKG, MRI)
☐Biospecimen collection (saliva samples, blood draws, hair samples, etc.)
☐Mobile applications/data collection devices (e.g., Fitbits, actigraphs, etc.)
☒Behavioral decision-making tasks (e.g., puzzles, interactive games, etc.)
☐Physical activities such as walking and other forms of exercise
☐Other procedures (briefly list types of procedures here if not covered by the check-boxes above): _____

7.0 Procedures Involved

Aim 1: Family caregiver participants (n=15) will test and provide feedback on the web-based negotiation and dispute resolution (NDR) tool. The NDR tool is comprised of two main platforms: a research study website which hosts negotiation training educational materials (print and video), as well as the web-based negotiation activity platform, Interactive Arbitration Guide Online (IAGO).

Since caregivers of older adults are often stretched for time (e.g. have full time jobs as well as that of caregiver, caring for children/older adults) and may find it difficult to attend in-person courses, we will offer the NDR training online using the Interactive Arbitration Guide Online (IAGO). IAGO is a platform for designing computer agents (AIs) that can negotiate with humans in a variety of game types. Platforms such as IAGO are used by many business schools (e.g. Kellogg, Harvard, Wharton) to enable easy access to negotiation learning, activities, and remote negotiations between multiple parties or computer simulation. With this negotiation-specific platform, we are able to build new or adapt current cases, assign negotiator roles, make pairings, and integrate surveys and downloading of feedback.

Caregiver feedback and usability testing will employ a user-centered design approach and inform refinements prior to the trial in Aim 2.

<u>Usability Testing of NDR Tool (N=15)</u>

Usability testing will occur across three cycles. Cycles 1 and 2 will be completed virtually with the study participant and the research study coordinator logged onto a Zoom

virtual meeting. This modality will allow us to utilize the screen share feature and record the session. By recording the Zoom session, we will be able to better specify what parts of the NDR tool correspond with participant feedback. This will be useful especially if participants run into functionality problems on any of the web-based platforms since it will allow us to provide our software developers with specific screenshots/recordings they may need to make revisions.

The research study coordinator will send a Zoom link to the research study participant's email address prior to their scheduled session. Participants will log on to the Zoom session where the research study coordinator will introduce themselves and send them the link to the research study website via chat once in Zoom. Once participants have logged on, they will share their screen with the research study coordinator. Below is a sequence of the NDR tool components the study participants will review and provide feedback on in Aim 1.

Usability testing is comprised of up to three cycles of study participant feedback. The first two cycles will include collection of qualitative and quantitative data. Participants will utilize the "think aloud" strategy to describe reactions while using the NDR tool and to help us identify any technical issues and/or glitches. The third, final cycle of feedback will involve the collection of quantitative data and a final qualitative assessment of the NDR tool with the study participants navigating through the entire tool on their own, completion of a brief online survey, and providing additional feedback via a semi-structured phone interview.

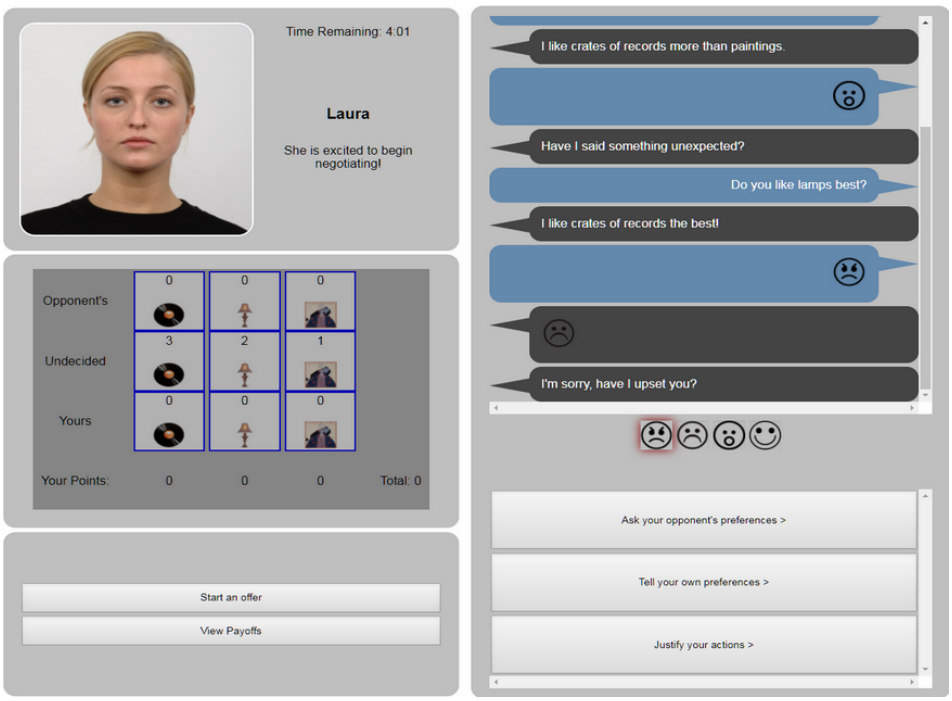
Research study website

First, study participants will view and provide feedback on the research study website. The research coordinator will solicit feedback specifically regarding the website's design, readability, functionality, and clarity of instructions.

(1) Interactive Arbitration Guide Online (IAGO)

Next, participants will access the IAGO platform utilizing the provided link embedded within the research study website. Participants will complete two negotiation activities and each activity session will take approximately 7-10 minutes. Below is an example of what the IAGO negotiation case interface will look like:

Figure 1. IAGO interface example



Study participants will complete both negotiation exercises in IAGO and the research coordinator will observe the interactions, paying particular attention to any technical problems and/or confusing elements to the study participant. Once the IAGO exercises are complete, study participants will provide feedback on the additional parts of IAGO: (1) tutorial, (2) content of the two* negotiation exercises, (3) individualized negotiation feedback generated by IAGO and (4) the overall usability of the IAGO platform and the negotiation exercises.

*Note: The NDR tool will host four negotiation exercises. In order to ensure sufficient feedback for all of the exercises, while also not burdening the research study participants by asking them to complete all four exercises, participants will all review negotiation Exercise 1. The study coordinator will then assign an additional exercise to each participant for two exercises per participant. The exercises differ based on conflict topic and who the negotiation role-play scenario involves. The four negotiation exercises are as follows: Exercise 1: Caregiver vs. Older Adult Patient - Easy [Constant: All participants will view this]; Exercise 2: Caregiver vs. Caregiver; Exercise 3: Caregiver vs. Physician; and Exercise 4: Caregiver vs. Older Adult Patient [Advanced].

(2) Negotiation Learning Materials: Resources & Videos

Next, study participants will be re-directed from IAGO back to the research study website, which hosts negotiation learning materials and resources. Participants will review three documents hosted on the resources page: (1) High Performance

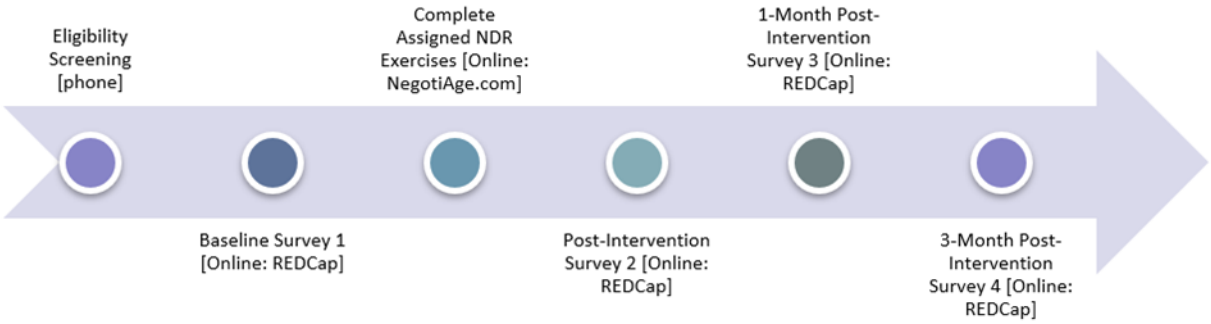
Negotiation Strategies checklist, (2) Interests-Rights-Power Negotiation Framework Summary and (3) Negotiation Planning template.

Additionally, study participants will watch five videos hosted on the study website related to the negotiation content and strategies. The videos will cover the interests/right/power negotiation framework and negotiation tactics. Each video is approximately three minutes long; the longest video is about seven minutes. The total time needed to watch all five videos will be approximately 20 minutes. We will ask for feedback about the resources in general with a focus on clarity and perceived utility.

Once all study participants complete Cycle 1, we will share the findings with the team and decide on modifications to the NDR tool based on the feedback/usability testing results. We will make user-driven refinements after each cycle of usability testing. We will repeat this process twice if needed. We anticipate it will take up to 3 months between the first and second cycles of feedback. Once we make changes to the NDR tool, we will repeat this process during Cycle 2 with the same set of study participants and repeat the procedures above, *only if there are sections that were refined based on Cycle 1 feedback*. We will again ask participants to interact with the NDR tool on Zoom and provide both qualitative and quantitative feedback.

After Cycle 1 and Cycle 2, which will only occur if needed, of usability testing are complete, we will email all study participants a link to the final NDR tool. If Cycle 3 is needed, participants will run through the NDR tool independently and then fill out an online survey hosted on REDCap. This survey will include a modified version of the USE Scale (a measure of usefulness, satisfaction, ease of use, and ease of learning) to measure the participant's final satisfaction with the tool. Additionally, we will ask participants to complete a brief, semi-structured interview over the phone to assess the overall NDR tool's acceptability, satisfaction, and overall impressions. This semi-structured interview will help enhance the quantitative data collected in Cycle 3.

Aim 2: All study timepoints will take place online (REDCap survey) with the exception of the study screener (phone) and e-CONSENT (participant will view online while research study coordinator is on the phone).



Baseline Survey 1: Participants who consent to participate in the study will be sent a link to the REDCap Baseline Survey 1 to their email address. The Research Study Coordinator will confirm that the Baseline Survey 1 link was received while they are still on the call with the participant after the e-Consent to ensure it was sent to the correct email address, was not in a Spam/Junk folder, etc. Participants will have 7 days to submit their completed Baseline Survey 1.
Anticipated participant time required to complete Survey 1: 35 minutes

Study Intervention - Assigned NDR Exercises: Once the completed Baseline Survey 1 is received from the study participant, the Research Study Coordinator will send them a unique study link which includes their embedded randomization assignment (pre-randomized) to their email. The link will give participants access to the study website, www.NegotiAge.com, as well as the negotiation platform where they will access their assigned NDR exercises, IAGO. Participants will have 14 days to complete their assigned exercises.
Anticipated participant time required to complete Study Intervention – Assigned NDR Exercises*: 10-30 minutes

*Participants will be randomized to which/how many negotiation activities they are required to do so we are providing a range of time.

Post-Intervention Survey 2: Once a participant has completed all of their assigned NDR exercises, the research study team will be able to access their completion status via an automated report. Participants who have completed all of their assigned study activities will be emailed a link for them to complete the Post-Intervention Survey 2 on the REDCap survey platform. Participants are expected complete the Post-Intervention Survey 2 within 7 days of completing all of the Assigned NDR Exercises.
Anticipated participant time required to complete Survey 2: 25 minutes

1-Month Post-Intervention Survey 3: Study participants will be emailed a link to Survey 3 which will be hosted on REDCap and is to be completed online. Participants will be sent this survey for completion one-month after completion of Survey 2. Participants are expected to complete the 1-Month Post-Intervention Survey 3 within ±14 days of being sent the survey link. If a participant misses either of the follow-up surveys (Survey 3 and/or Survey 4), they will continue to be enrolled in the study.
Anticipated participant time required to complete Survey 3: 25 minutes

3-Month Post-Intervention Survey 4: Study participants will be emailed a link to Survey 4 which will be hosted on REDCap and is to be completed online. This is the final study activity. Participants will be sent this survey for completion three-months after completion of Survey 2. Participants are expected to complete the 3-Month Post-Intervention Survey 3 within ±14 days of being sent the survey link.
Anticipated participant time required to complete Survey 4: 30 minutes

Data collection instruments by time-point listed below:

Data Collection Instrument	Consent (1)	Enrollment (2)	Survey 1 - Baseline (3)	Survey 2 - Post-Intervention (4)	Survey 3 - 1-Month (5)	Survey 4 - 3-Month (6)
e-Consent (survey)	✔					
Post-Consent - Survey 1 Instructions		✔				
Participant Contact Information		✔				
Participant Communication Log		✔				
Screener		✔				
Enrollment Status		✔				
Study Completion Compliance		✔				
Gift Cards - Survey 1		✔				
Gift Cards - Survey 2		✔				
Gift Cards - Survey 3		✔				
Gift Cards - Survey 4		✔				
Positive Affect & Wellbeing (survey)			⬇		⬇	⬇
PROMIS SF - Anxiety (survey)			⬇		⬇	⬇
Caregiver Burden - Zarit (survey)			⬇		⬇	⬇
Neuro-QoL Caregiver SF - TBI-CareQOL Caregiver-Specific Anxiety (survey)			⬇		⬇	⬇
PROMIS SF - Fatigue (survey)			⬇		⬇	⬇
PROMIS SF - Emotional Support (survey)			⬇		⬇	⬇
PROMIS SF - Satisfaction Roles Activities (survey)			⬇		⬇	⬇
PROMIS SF - General Self-Efficacy (survey)			⬇		⬇	⬇
Sociodemographics (survey)			⬇		⬇	⬇
Acceptability - USE (survey)				⬇		
Usability - SUS (survey)				⬇		
Dutch Test for Conflict Handling (DUTCH) (survey)			⬇	⬇	⬇	⬇
Negotiation Knowledge (survey)			⬇	⬇	⬇	⬇
Negotiation Utilization (survey)					⬇	⬇
PANAS (survey)			⬇		⬇	⬇
IAGO Post-Assessment [Perceived Success] (survey)				⬇		

For the purposes of distributing and mailing study compensation, as well as collecting contact information necessary for data collection, the following identifiers will be collected in Aim 1 and Aim 2 of this study:

- Participant name
- Mailing address
- Email address
- Phone number

At the conclusion of the study, once final study analysis is complete, study participants will receive a summary of the findings in layman terms and next steps. In addition, upon request, study participants will receive a copy of this study's primary findings manuscript once it has been published.

8.0 Research with Vulnerable Populations (if children are the ONLY vulnerable population you plan to enroll, do NOT complete this section -- instead fill out Appendix A):

N/A

9.0 Incomplete Disclosure or Deception:

N/A

10.0 Consent Process

Aim 1: Informed consent (electronic) will be obtained by Northwestern research study coordinator using the REDCap e-consent application after the participant is deemed eligible to participate after completing the study screener. Informed consent will be viewed as a process, i.e., at several times during review of the IRB approved consent document, the participant will be asked to explain in his/her own words what his/her understanding of the consent. This will enable the research personnel to enter into a dialogue with the participant and ensure that the participants understands that he/she is free to withdraw at any time without penalty. We will provide information to the participants in terms that they can fully understand. There will be no exertion of any overt or covert coercion. The e-consent document is written in language that the potential participant can understand, and they will be encouraged to ask questions prior to giving consent.

A copy of the signed e-consent form will be downloaded from REDCap and uploaded into Study Tracker as well as saved on the FSMResFile shared project folder. All study participants will receive a copy of the signed e-consent form via email to their preferred email address.

Aim 2: Research study coordinators using the REDCap electronic (e-consent) application will obtain informed consent. If the individual is eligible and is interested in participating, they will be sent a link to the electronic-consent form (e-consent) to their preferred email address. The Research Study Coordinator will explain the study to the participant over the phone, and both the participant and research coordinator will go through the e-consent together.

If the participant does NOT have time to complete the e-consent after the screening assessment and/or does not have access to view/sign the e-consent that day, the Research Study Coordinator will schedule a day/time for completion of the e-consent with the participant. If the participant agrees to participate, they will sign the consent form electronically. The research staffer will also sign and date the form electronically.

Informed consent will be viewed as a process, i.e., at several times during review of the IRB approved consent document, the participant will be asked to explain in his/her own words what his/her understanding of the consent. This will enable the research personnel to enter into a dialogue with the participant and ensure that the participants understands that he/she is free to withdraw at any time without penalty. We will provide information to the participants in terms that they can fully understand. There will be no exertion of any overt or covert coercion. The e-consent document is written in language that the potential participant can understand, and they will be encouraged to ask questions prior to giving consent.

A copy of the signed e-consent form will be downloaded from REDCap and uploaded into StudyTracker as well as saved on the project's secured shared drive folder. All study

participants will receive a copy of the signed e-consent form to their preferred email address.

11.0 Waiver of Participant Signature on Consent Form: N/A

We are not requesting a waiver of participant signature on the consent form since signature will be obtained remotely using the REDCap platform for both study Aims 1 and 2.

12.0 Waivers and Alterations of Consent Information: N/A

13.0 Financial Compensation:

Aim 1: We will compensate study participants for their time and the amount of the compensation will depend on which study activities they complete. We anticipate that the study participants will spend up to 8 hours on the usability testing (approximately 2-3 hours per each cycle). Subjects will be compensated only for the study activities they complete. Compensation was determined by using a rate of $50/hour for each activity.

Activity	**Estimated Duration**	**Visa Gift Card Value**
Cycle 1: Initial usability testing of NDR Tool	Up to 3 hours	$150
Cycle 2 (if needed): Usability testing of NDR Tool refinements	Up to 2 hours	$100
Cycle 3 (if needed): Final usability testing		
Survey 3a. Final review & REDCap survey	Up to 2 hours	$100
Survey 3b. Semi-structured phone interview.	Up to 1 hour	$50
TOTAL	Up to 8 hours	Up to $400

We will compensate research study participants with Visa gift cards. They will receive compensation within 4 weeks of their completion of the study activities. Since the study activities are completed remotely, the Visa gift cards will be mailed to study participants at their specified mailing address. Participants will be compensated the full amount even if they do not spend the estimated duration period on the activity (e.g. if a participant only spends 2 hours on Cycle 1, they will be compensated $150, not $100).

We will not compensate study participants for study activities they do not complete. However, they will still be allowed to participate in Aim 1 of the study if they do not complete all three activity cycles (e.g. if they only complete Cycle 1 but not Cycle 2, they are still eligible to complete Cycle 3). Participants will not incur any costs in participating in this research study.

Aim 2: All enrolled participants will be compensated for their time and effort for the completion of each activity in Aim 2. Participants will receive up to $500 in virtual Visa gift cards. Participants will only receive compensation for the activities that they complete. However, participants will still be allowed to continue their participation in the study even if they do not complete all the study activities. All activities will be completed online and the corresponding compensation upon completion is listed 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		**$500**

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

Virtual Visa gift cards will be emailed to study participants upon completion of each study activity no later than 5 days after each activity completion. The research study coordinator will call or email participation to confirm receipt of the virtual gift card and log all compensation mailings on the Aim 2 Participant Compensation Log. Participants will not incur any costs in participating in this research study.

We are not able to receive a signed receipt from the study participants for either Aim 1 or Aim 2 given that these study activities will take place virtually. The Research Study Coordinator will sign and date a receipt including the study participant ID and date of survey completion along with the compensation amount. This receipt will be kept electronically on the shared drive. In addition, a compensation tracking log will be tracked in Excel which will include the following fields: study ID, type of survey/activity completed, date survey/activity completed, Visa gift card number, ICN number, date gift card mailed, value of gift card, and the initials of the Research Study Coordinator who emailed the compensation.

14.0 Audio/Video Recording/Photography

Aim 1: Northwestern research staff will record the online Zoom sessions during Cycle 1 and Cycle 2 of usability testing. Recordings will include audio of the Zoom sessions as well as video recordings of the screen share sessions. Recordings data will be used to aid in identifying any issues in usability/functionality across the NDR Tool web-based platforms. Recordings will also allow us to transcribe their responses to the feedback

questions so that we capture data accurately. Agreeing to have the Zoom feedback sessions recorded in Cycle 1 and Cycle 2 is ***mandatory*** for study participation.

Cycle 3, which includes a semi-structured survey over the phone, will not take place over Zoom however it will be audio recorded to allow us to transcribe their responses to the questions so that we capture their responses accurately. Agreeing to have the Cycle 3 phone session recorded is ***not mandatory*** for study participation. If participants do not agree to be recorded, we will ask for additional time to allow us to capture their responses in real time.

Zoom recordings will be directly saved to the desktop. Once the participant interview is complete, the recordings will be moved to the shared study folder on the Feinberg managed servers (FSM/NUCATS Managed storage), specifically on the GIM/GER shared research drive (specific project folder on the Research drive in GIM/GER) with no identifying information for the duration of the funded study, unless other arrangements are made.

Audio from Cycle 3 will also be stored on the GIM/GER shared research drive (specific project folder on the Research drive in GIM/GER). The study PI and Northwestern research staff on the IRB of this study will have access to the files as needed. Participants may request that audio files be deleted before the end of the study, in which case we will comply.

Aim 2: N/A

15.0 Potential Benefits of this Research:

Aim 1 and Aim 2: Participants may experience a direct benefit from being a part of this research study since they will be exposed to negotiation and dispute resolution activities and may gain useful knowledge as a result. However, we cannot guarantee that they will directly benefit from being part of the study. They may however 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/dementia.

At a population level, the proposed study can lead to meaningful improvement in the lives of family caregivers and people with Alzheimer's Disease and memory loss. Although benefits to individual participants may be minimal, the potential benefits of this study at a population level should greatly exceed the minimal risk to individual subjects.

16.0 Potential Risks to Participants:

Aim 1: There are minimal risks to participation. Potential risks to study participants include: potential loss of confidentiality and emotional discomfort in participating in potentially stressful scenarios and answering questions on surveys related to conflict.

Confidentiality may be broken by research staff to ensure the study participant's safety if there is an imminent threat to self or others. All of these potential losses of confidentiality are disclosed in the consent documents. All potential risks associated with participation in this study are disclosed in consent documents. The procedures to protect against risks associated with potential loss of confidentiality include: keeping participant data strictly confidential, except as mandated by law (see section 18.0 where data security measures are described).

Procedures to protect against risk associated with experiencing emotional discomfort in answering survey questions and/or completing conflict activities include information participants that they can decline to answer any questions they choose. Likewise, they will be informed that they do not have to complete any negotiation activities that they choose not to. Negotiation and dispute resolution training programs generally have not been shown to cause any harm. Participants can elect to stop the training activities at any time. Participants will give voluntary responses to interview questions; they are told that they can decline to answer any questions that they choose.

We will inform participants that their involvement in the study is voluntary, and they may withdraw from the study at any time. We do not anticipate any circumstances where a participant would be withdrawn from the research without their consent.

Aim 2: There are minimal risks to participation. Potential risks to study participants include potential loss of confidentiality and emotional discomfort in participating in potentially stressful scenarios and answering questions on surveys related to conflict.

Confidentiality may be broken by research staff to ensure the study participant's safety if there is an imminent threat to self or others. All these potential losses of confidentiality are disclosed in the consent documents. All potential risks associated with participation in this study are disclosed in consent documents. The procedures to protect against risks associated with potential loss of confidentiality include keeping participant data strictly confidential, except as mandated by law.

Procedures to protect against risk associated with experiencing emotional discomfort in answering survey questions and/or completing conflict activities include information participants that they can decline to answer any questions they choose. Likewise, they will be informed that they do not have to complete any negotiation activities that they choose not to. Negotiation and dispute resolution training programs generally have not been shown to cause any harm. Participants can elect to stop the training activities at any time. Participants will give voluntary responses to survey questions; they can decline to answer any questions that they choose when they are completing the study surveys online.

We will inform participants that their involvement in the study is voluntary, and they may withdraw from the study at any time. We do not anticipate any circumstances where a participant would be withdrawn from the research without their consent.

17.0 Provisions to Protect Participant Privacy and Data Confidentiality:

Aim 1:

Participant Privacy. In all research documentation, a unique identification number ("Study ID") will identify participants, not by name, and any other identifying information (e.g. personal and/or contact information) will be kept separate from the other data; all information will be kept in secure, password protected files. This also includes Zoom video and audio files for those participants in Aim 1. We will ask participants to try and refrain from using any identifiers during recorded sessions. Further, unless required by law, only the study investigators, members of the research project staff, and representatives of the Northwestern University will have the authority to review any study records. In such case, they too will be required to maintain confidentiality.

Confidentiality of Data. Information from participants will not be linked to their name and will be assigned a unique identification number. The research database will be password protected and accessible only to the research team and the Institutional Review Board. Information linking participants with their unique identifier will be kept on a separate password-protected desktop computer in a locked office within an Administrative Suite in the Division of General Internal Medicine and Geriatrics, Northwestern University. Information linking subjects' names and contact information with their unique identified will be kept in a separate password protected file. Copies of the signed, electronic consent forms will be kept in a locked cabinet only accessible by the research team and a copy will be either mailed to the study participant or emailed, depending on their preference. When demographic data is entered into the database, a de-identified subject number will be used to identify research subjects. No individuals will be identified in any presentations or publications resulting from this research.

Data Access. The Data Custodian is the Principal Investigator, Dr. Lee Lindquist. Only authorized personnel listed on in the IRB will have access to the data. Any information that could allow identification of individual participants, including the master list, will be kept strictly confidential.

Local Data Storage. Data will be stored in REDCap, a secure, web-based application, and on FSM/NUCATS Managed storage, specifically on the GIM/GER shared research drive (specific project folder on the Research drive in GIM/GER) for the length of the study. We will transcribe qualitative data as needed and save in Microsoft Excel for coding.

Quantitative data will be exported to data analysis software such as STATA or SAS. These data files will not contain any identifiable information, and will be identified by project staff with an assigned study ID. Upon completion of all study activities, we will create a final de-identified dataset an all-identifiable information will be deleted. This dataset will be stored indefinitely on the FSM/NUCATS managed storage, specifically the GIM shared research drive for secondary analyses. Only authorized personnel will have access to the dataset and study folder. We will delete identifiable information upon completion of the study. Zoom audio and video recordings three years after completion of the study per Northwestern University policy.

Aim 2:

Participant Privacy. In all research documentation, a unique identification number ("Study ID") will identify participants, not by name, and any other identifying information (e.g. personal and/or contact information) will be kept separate from the other data; all information will be kept in secure, password protected files located on secure project folders on the shared drive. Further, unless required by law, only the study investigators, members of the research project staff, and representatives of the Northwestern University will have the authority to review any study records. In such case, they too will be required to maintain confidentiality.

Confidentiality of data. We will not include participant identifiers (e.g. contact information such as name, residential address, phone number, email address, etc.) together with the study data. We will have a separate database which is password protected and accessible only to the research team and IRB which will house the identifying information (REDCap). The study data from the REDCap surveys will be assigned a unique identification number and will not be linked to their name.

Copies of the signed, electronic consent forms will be saved on the shared project drive and will also be uploaded into Study Tracker. When demographic data is entered into the database, a de-identified subject number will be used to identify research subjects. No individuals will be identified in any presentations or publications resulting from this research.

Data transmitted between web data collection and study servers for internal study purposes will be encrypted and password protected in transmission and will be housed securely on study servers. No identifiable information will be contained in the data transmitted between web data collection and the study servers.

Study research data, including consent forms, will be kept for a minimum of 3 years after the completion of the study on the password protected study folder located on the encrypted shared research drive.

18.0 Data Monitoring Plan to Ensure the Safety of Participants:

This study did not meet the NIH/NIA requirements for a Data Safety and Monitoring Board (DSMB), but it does require a Safety Officer (SO). The SO is an independent individual who performs data and safety-monitoring activities in lower risk, but greater than minimal risk single-site clinical trials. The SO will advise the NIA Program staff and the Principal Investigator (PI) regarding participant safety, study risks and benefits, scientific integrity, participant recruitment, and ethical conduct of a study.

Our SO, Dr. Mara Schonberg has been approved by the NIA and has been added to the study IRB along with her human subjects training certificate. In **Aim 2**, the SO will receive the manual of operating procedures, which will contain the IRB-approved study protocol and data safety-monitoring plan, before study enrollment begins in **Aim 2**. The tasks of the SO will include reviewing the entire IRB-approved study protocol regarding subject safety and analysis, the informed consent document regarding applicability and readability, and participant recruitment and retention milestones.

Once we launch **Aim 2** of the study, every six months the study team will prepare safety reports to be reviewed by the SO and NIA for recommendations for or against the trial's continuation, as well as any modification to the study. The SO is un-blinded to safety data, but not necessarily to outcome data. In addition to safety data, the SO will consider recruitment and retention rates. For instance, they will consider whether delayed recruitment raises concerns of futility and other ethical considerations.

19.0 Long-term Data and Specimen Storage and Sharing:

Data will be stored on FSM/NUCATS Managed storage, specifically on the GIM/GER shared research drive (specific project folder on the Research drive in GIM/GER) and REDCap survey platform. Data collected on FSM department desktop and laptop computers is encrypted. Study data, which includes video and audio files, will not include identifiers. We will store data in the Feinberg Division of General Internal Medicine and Geriatrics for a minimum of three years after the project period has ended as per the Northwestern University Office of Sponsored Research. Destruction of research data will then follow applicable federal regulations, Northwestern policies on record retention and data disposal, sponsor requirements and other applicable guidelines.

20.0 Qualifications of Research Team to Conduct the Research:

This project is led by Dr. Lee A. Lindquist, along with Drs. Rogalski, Kim, and Pfammatter. Dr. Lee Lindquist is a geriatrician and Section Chief of Geriatrics at the Northwestern University Feinberg School of Medicine. Dr. Lindquist has extensive expertise in older adults, caregivers of seniors, caregiver support for patients with Alzheimer’s Disease and outpatient safety. She also has extensive experience collaborating in research with

community organizations and community members for recruitment, study implementation, data collection, and dissemination.

Dr. Kim is a biostatistician at the Northwestern University Feinberg School of Medicine and is very experiences in clinical trials, handling data transfer, harmonization, and workflow from REDCap. He has previously worked with Dr. Lindquist in submitting and implementing various studies.

Dr. Pfammatter is a Clinical Health Psychologist with expertise in the development and testing of technology to influence health behaviors. Her research has focused on optimizing the efficiency, fidelity, and reach of interventions using technologies such as web, smartphone, and smartwatch applications and the Multiphase Optimization Strategy (MOST) and her clinical background has primarily been in a context of collaborating in a multidisciplinary team to approach patient care, which informs the interventions she has developed. Dr. Pfammatter will utilize her expertise in MOST to guide the design and implementation of this study with the goal of preparing and optimizing a scalable intervention to improve caregiver outcomes.

Dr. Jonathan Mell is an Assistant Professor at the University of Central Florida and has a PhD in Computer Science (specifically in Human-Computer Interaction). His research centers on human-computer interaction with specific interests in emotion, automated negotiation, behavioral game theory, and artificial intelligence. He designs AIs that are capable of understanding human social interactions, and craft software and user experiences that allow the melding of technology and society. Dr. Mell is the creator and expert of the online negotiation software we will use, IAGO.

Dr. Lindquist, as the study PI, will personally train and supervise the Northwestern research staff in the day-to-day execution of the study details. Although Dr. Lindquist will have executive decision-making over all final research decisions, the research study coordinator will be the first point of contact “on the ground,” with close access to and constant communication with Dr. Lindquist. Any IRB revisions or updates will be submitted by the research manager or research coordinator, in addition to other administrative tasks (e.g. tracking of participant compensation, etc.).

Team Meetings: The entire investigator team (Lindquist, Rogalski, Pfammatter, Kim), and research staff (research manager, research coordinator) will meet approximately once a month. The PI and research staff will meet weekly and meet with the consultants as needed. Dr. Lindquist and the research study coordinator will be responsible for presenting interim outcome data, including the number of participants screened, enrolled, refused, and any anticipated or unanticipated obstacles encountered.