Emory University
Long Form Consent to Send to Caregivers by Mail
For a Research Study

Study Title: **Distance Savvy: Testing Tele-Savvy, a Distance Dementia Family Caregiver Education Program**

NCT Number: NCT03033875

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Introduction and Study Overview

Thank you for consenting to participate in our educational research study. This form is a more in-depth explanation of all study details compared to the phone conversation with the research staff before you consented to participate in this study. While you have already given consent to participate by reviewing the study information and discussing any questions you may have had with the project coordinator, we provide this full-length form to all caregivers who agree to participate. If you have not consented to participate yet but would like to read the full consent form first, we provide this form as well. Since this is a verbal consent process, you do not need to sign this form and return it to the project coordinator. It is yours for your records. If, after reading this form, you have any questions or concerns about your participation, please contact the project coordinator and we will gladly answer any of your questions. At any time, you can change your mind and withdraw from the research study.

By having indicated your consent, you will not give up any legal rights.

1) **Purpose of the Study and General Overview.** The purpose of this study is to test an on-line (internet-based) version of a well-established in-person group program that provides information and education to informal caregivers (family and friends) of persons with Alzheimer's disease (or related illnesses). The original education program – The Savvy Caregiver (Savvy) – has been shown in previous research to add to caregivers' skills and knowledge and to reduce the distress that caregivers often experience in this role. Tele-Savvy allows caregivers to participate in the Savvy Caregiver program at a distance. While Tele-Savvy program has already been tested in a small-scale study and the results have confirmed its efficacy, the current study is of larger scale. The small-scale Tele-Savvy was managed only in Atlanta and recruited over 50 caregivers. For the large study, we recruited over 200 caregivers in four research centers. For those caregivers who were interested and/or consented to the large study and were not able to be placed in a group, we have created a small-scale Modified Tele-Savvy group.

2) **Three Parts of the Study.** If you choose to participate in the Modified Tele-Savvy group, you will be placed in the Tele-Savvy group right away. The modified Tele-Savvy groups follow the same format (described in detail below) and duration (43 days) as the original Tele-Savvy. The only difference is the Modified Tele-Savvy group will not take part in the weekly video conferences. Like the original group, the Modified Tele-Savvy will teach effective caregiving strategies and ways to modify your caregiving to improve the quality of life for you and the person for whom you are caring. Below is the detailed description of steps involved in the preparation for participation in the study.

3) **General Structure of the Study. Part 1: Videos.** Tele-Savvy Educational Program are delivered on a computer or another mobile device with an internet connection. The programs extend over a six-week period (43 days). The first component of the program is viewing daily videos (6 days per week. Each week, you will be asked to view brief daily instructional videos on your computer (7-15 minutes each). You will view these videos on an educational Canvas web-site that you will be trained to use. You can watch the videos at a time that is convenient for you and you can re-watch them. You will be trained on how to access videos and your navigator (research team member) will be available for technical support.

4) **Research Staff.** You will have contact information of Principal Investigators and co-investigators of this study. When you prepare for the study, you will primarily interact with your navigator who will help you will all aspects of study orientation, training to use technology, and will be available for technical support throughout the entire program. Your navigator will be the first point of contact for all aspects of the study. Additionally, you will interact with a data collector who will conduct interviews throughout the study.

Your involvement in this study will take about six months. Here's what will happen.

Prior to Participation

5) **Consent.** After the project coordinator contacts you and you indicate an interest in this study and are eligible to partake, the project coordinator will provide you with the full informed consent form (this document). The project coordinator will read you oral consent document and ask you whether you would like to participate in this study. This may be immediately in the same telephone conversation. If, however, you want to review the document in advance, the project coordinator will email or mail them to you and schedule a time for a follow-up call when she could go in greater detail about the study and formally ask you whether you agree to participate or not.

6) **Scheduling Baseline Data Collection.** At the end of the conversation when you consent to participate, the project coordinator or a research team member will schedule the next telephone conversation with you during which a data collector will teach you how to use videoconferencing tool Zoom and conduct baseline assessment interview. For this interview (orientation to Zoom and baseline data collection) we kindly ask that you schedule about 90 minutes and have your computer and webcam available. (It is possible that this data collection interview can be divided into two halves if necessary).

7) **Webcam.** Finally, the project coordinator will ask you whether you have a webcam. If not, the project coordinator will mail you the webcam for the duration of the program, so that you can install it before the baseline interview. The reason for this is that you would need a webcam for participation in 3 data collection interviews. In this study, interviews occur via videoconferencing with the use of a webcam. When you conduct the first baseline assessment interview, the data collector will help you install the webcam if needed. Webcams are very easy to use and only require that you plug a webcam into a USB port. We do not charge for webcams but we may kindly ask

participants to return webcams after the entire program is over (in approximately 6 months after you sign up for this study; paid return postage will be provided).

8) **A) Baseline Interview Step 1: Connecting to Zoom.** At a designated time as scheduled with the project coordinator, a data collector will call you to go over videoconferencing tool Zoom and collect data in a baseline interview. First, when the data collector calls you, she will verify that you have the webcam installed and she can help with installation if necessary. Second, the data collector will email you a link to join her for a videoconference. This is a straightforward procedure and as soon as you open the link, you are led to a virtual "room," where you will see the data collector and be able to talk to her. As soon as connection is established, you can hang up on your phone, however, should technical difficulties arise, the data collector will call you right back and help troubleshoot teleconferencing.

   B) Baseline Interview Step 2: Baseline Data Collection. As soon as teleconferencing connection is established, the data collector will begin baseline interview. For some of the questions, she will share a screen with response scales, so that you can see them in front of you and do not have to memorize different scales for different questions. The interview will take about an hour. Please feel free to ask the data collector to stop the interview at any time so that it can be resumed later. Likewise, you are always free to skip any questions and not answer any questions that you are not comfortable answering. This will apply to any data collection interview throughout the program. All information obtained in all interviews in this study is confidential and the papers where the data collector will record your answers will only have artificially created numeric identifiers, and the code for these numeric identifiers will be stored in a secure location separate from paper or electronic forms with your answers. This way, only the data collector will know your responses, but the rest of the study staff will receive de-identified data.

   C) Baseline Interview Step 3: Orientation to Zoom. If you would like to go over navigating in Zoom after the baseline interview, the data collector will remain in the videoconference with you to train you how to use it. Otherwise, please tell the data collector that you would prefer to schedule a different call to go over Zoom – in that case, your navigator will orient you to Zoom in a separate call. If you choose to go over Zoom immediately after the baseline interview, the data collector will help you practice muting and unmuting your microphone, using chat while in the videoconference, adjusting your camera for the best positioning and lighting, adjusting the sound, and leaving the teleconference.

   D) Baseline Interview Step 4: Mailing Address. At the end of the first interview, the data collector will ask you to provide your mailing address where program materials (described in detail below) will be mailed.

9) **Orientation to Canvas.** When your navigator calls you, she will teach you how to access the Canvas web-site where the videos will be stored (you can think of Canvas as a virtual home for your study activities). You can practice opening the videos and making sure that they are of high quality and have adequate sound while you are on the phone with the navigator. The navigator will help you adjust the computer settings (e.g., sound) and ensure that videos are working adequately on your computer. You will be provided with a simple to use, illustrated step-by-step guide to access the

videos. Additionally, your navigator will be available at all times during your participation in the program for any technical assistance.

10) **Other Uses of Canvas Web-Site.** Additionally, you can access program materials from Canvas web-site, such as syllabus, program schedule, and guides for using technology (we will also mail hard copies of these materials to you). Canvas web-site also has a Discussion board where you can leave your comments and/or questions for the research staff. Likewise, you will be able to rate the quality of videos and leave comments for the videos on Canvas.

11) **Program Materials: Tele-Savvy**. Once the first interview is completed, we will mail you a set of materials that are part of the program. All of these materials are free and are yours to keep after the end of the study. For the Modified Tele-Savvy group, you will receive a caregiver's manual that is like the textbook for the course, a workbook used during the course, and course syllabus with topics for each week of Tele-Savvy and non-mandatory reading assignments from the manual. You will also receive a calendar indicating when the course will start and indicating when you will receive daily instructional videos. Next, we will provide step-by-step written illustrated guides to access Canvas web-site for your daily videos. Course calendar, syllabus, and illustrated guides will also be available on the Canvas web-site and we will email course calendar, syllabus, and illustrated guides to you as well. We will e-mail you daily reminders to watch Tele-Savvy videos on Canvas web-site every day of the week. If throughout the program you encounter instances where you think you might need additional instructions for any technical aspects of the program, please notify your navigator and we will create written illustrated guides for any elements that may need extra clarification. It is our goal to make technological aspect of the program easy and seamless for you. In the previous pilot version of Tele-Savvy no caregivers discontinued their participation because of technological difficulties regardless of their prior experience with videoconferencing.

12) **Data Collection: Important Note.** After you have completed baseline data collection, you will be asked to complete up to 2 more very similar interviews with a data collector. They will occur according to the following timeline: 3 and 6 months after your baseline interview.

The Tele-Savvy Program – Your Participation.

13) **Daily videos.** Each of the 36 daily modules will include brief video "lessons" (7-15 minutes each) that provide information about Alzheimer's and other dementias and about strategies that you can use to deal with the losses that dementing illnesses produce in your loved one. Some of the videos focus, also, on ways you can care for yourself and ways to increase the help you have for your caregiving. Some of the videos may be followed by a very brief set of 4-10 questions related to the content of the lesson. We would very much appreciate your comments to videos which you can write after each video in a dedicated space in Canvas.

After Your Participation in the Program.

14) We want to know how useful the program was for you and what you thought of it. So there are two kinds of procedures in which we will ask you to take part: questionnaire interviews and a more in-depth conversation-style interview about your experience with the program.

A) Post Program Questionnaires. Data collection interviews will always be scheduled by your data collector: she will contact you to set up a time during which data collector will call you to do the interview. The same procedure will apply to each of the 3 interviews: baseline, and 3 and 6 months post-baseline. We kindly ask that you have about 60 minutes scheduled for each interview. In each case, data collector will e-mail you a link to join her on videoconference at a scheduled time and if technical difficulties occur, she will call you on your phone to troubleshoot.

B) De-Briefing Interviews. We will ask about 8-20% of the entire sample of caregivers participating in this study to have a more in depth conversation about Tele-Savvy. We will be looking for suggestions about ways to improve the program and for your judgments about which parts of the program were especially effective or that were especially not effective. We will record the conversations and have them transcribed so that the research team can look for themes among the responses (the transcripts will not identify you by name). Each de-briefing interview will take about 60 minutes and the time of each interview will largely depend on how much feedback on the program you may want to give. We highly appreciate all feedback, both positive comments and suggestions for improvement for the program, so we encourage participants to share any ways they see the program can be strengthened and better serve caregivers. Your feedback will be confidential and your comments will be reported only in a de-identified format.

15) Risks and Discomforts

Caregiving is known to be a stressful role. Thinking about the role or the person for whom care is being provided (for instance while watching a video segment about caregiving) might produce discomfort. Likewise, answering questions about caregiving or its effects on you might produce discomfort. So the individual and group parts of the program itself and the questionnaires we will ask you to fill out during interviews pose some minimal risk for emotional distress.

Participants will be given phone numbers to use to reach the project coordinator, the navigator and investigators if material contained in the program produces emotional distress. The investigators will be able to make referrals to sources that may be of help. For emergent circumstances, referral to a local emergency room setting will be made.

Additionally, participation in the program and completion of interviews may add pressure to your schedule. However, we make every effort to schedule training, orientation and interviews at times that are convenient for you, including weekday business hours and evenings and weekends. We will prioritize not exceeding the limit of 60 minutes for interviews. Data collector can always break up interviews into several parts in case you need to take a break and resume later. Homework reading assignments are not mandatory and are not meant to burden your schedule but rather may be used as a reference or you may read this material after the program is over.

All of the data gathered through the questionnaires and interviews will be stored or recorded using identification codes that will be kept separately from the information itself. The data, once coded, will be stored and used on password-protected computers, and the completed questionnaires will be stored in a locked file cabinet in the project office. The debriefing phone calls will likewise not

identify you except by first name, and we will remove all identifiers from the transcripts. Any reports or publications that might result will assure anonymity.

16) New Information

It is possible that we will learn something new during the study about the risks of being in it. If this happens, we will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

17) Benefits

This study is testing the efficacy of an on-line educational program for a variety of dementia caregivers from across the U.S., so we cannot tell you that you will benefit from it. While the research study is not designed to benefit you directly, it is certainly our hope that the information will be of use and benefit. This study is designed to learn more about the feasibility and effect of a caregiver education program that is delivered at a distance through web-based methods. The study results may be used to help others in the future.

18) Compensation

You will be paid a $25 gift card for your time and participation for each interview.

19) Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the Emory Institutional Review Board, and the Emory Office of Research Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Study records can be opened by court order. They may also be produced in response to a subpoena or a request for production of documents.

We will do everything we can to keep others from learning about your participation in the research.

20) Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. The only information we will gather that can be considered Protected Health Information will be your name, age, date of birth, mailing address, e-mail address, and phone number. We will ask you if you are caring for a person with

Alzheimer's disease or another dementing illness, but we will not ask you to identify this person by name. To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that will be Used/Disclosed:

The only PHI that we will use and/or disclose (share) for the research study includes

- Your name, mailing address, e-mail address, phone number, date of birth, and age.

21) Purposes for which your PHI will be Used/Disclosed

We will use and disclose your PHI for the conduct and oversight of the research study. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards, and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

22) Use and Disclosure of Your Information that is Required by Law

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report abuse of elder or disabled adults as we are mandatory reporters. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

23) Authorization to Use PHI is Required to Participate

By providing your oral consent, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the study, then you may not participate in the research study. If you are a patient/client of Emory Healthcare, you may still receive non-research related treatment.

24) People that will Use and/or Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigators and the research staff will use and disclose your PHI to conduct the study and give you study-related treatment.

- The Principal Investigators and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The National Institute on Aging, a division of the National Institutes of Health, is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory Institutional Review Board and the Emory Research and Healthcare Compliance Offices.
    - Government agencies that regulate the research including the Office for Human Research Protections.
    - Research monitors and reviewer.

25) Expiration of Your Authorization

This authorization will not expire because it is a research study.

26) Revoking Your Authorization

If you provide oral consent, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must write to: Kenneth Hepburn, PhD; Emory School of Nursing; *redacted*

At that point, the researchers will not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data are correct. If you revoke your authorization you will not be able to stay in the study.

27) Other Items You Should Know

Not all people and entities are covered by the Privacy Rules. Privacy Rules only apply to health care providers, health care payers or health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health

care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations and/or for other purposes besides this study.

28) Costs

There will be no costs to you for participating in this study, other than basic expenses like maintaining your internet service. You will not be charged for any of the research activities.

29) Voluntary Participation and Withdrawal from the Study

You have the right to leave a study at any time without penalty. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer.

The researchers and funder also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- Or for any other reason.

30) Contact Information

Contact Kenneth Hepburn at *redacted*

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.