Informed Consent Form

Title: Producing a Fully Asynchronous Online Savvy Program

NCT Number: NCT04951037

IRB Approval Date: August 19, 2020

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 80 people who are being studied, at Emory.

Why is this study being done?
This study is being done to answer the question: How does a fully online, self-administered psychoeducation program can enhance caregiving mastery of family and friends who provided unpaid care for persons living with Alzheimer's and similar dementia disorders (PLWD)? You are being asked to be in this research study because you are family caregiver of a person living with dementia.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for up to four months. The researchers will ask you to do the following: participate in a fully online version of the Tele-Savvy program for 42 days, pre and post-survey, and in-depth interviews.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question.

What are the risks or discomforts I should know about before making a decision?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include loss of privacy, and breach in confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
You will not have to pay for any of the study procedures.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Aim 2

Title: Producing a Fully Asynchronous Online Savvy Program

Principal Investigator: Fayron Epps, PhD, RN and Carolyn Clevenger DNP, RN; Nell Hodgson Woodruff School of Nursing

Funding Source: National Institute on Aging

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this study is to develop and test a fully online, self-administered psychoeducation program to enhance the caregiving mastery of family and friends who provide unpaid care for persons living with Alzheimer's and similar dementia disorders (PLWD).

Procedures

You will be asked to participate in a fully online version of the Tele-Savvy program. In this version, you will receive a series of daily video lessons related to caregiving. These lessons are generally 8-15 minutes in length. A link to them will be emailed to you on each program day. You can watch them whenever and as often as you wish over the course of the study. You will also participate in self-guided learning strategies and exercises to accomplish skill and mastery related to your caregiving role. The lessons cover a variety of topics including:

- Facts about dementing Illnesses
- Caregiving Strategies – guiding the person through days that are as safe, calm, and pleasant as possible
- Self-Care for the Caregiver

You will also be asked to participate in pre and post-surveys before the start of the program and 2 months and 3 months after participation in the fully online version of the Tele-Savvy program to assess your caregiving mastery and well-being. You may also be asked to participate in in-depth interviews to assess the feasibility of the program.

Risks and Discomforts

There is little risk too you for participating in this study. The major risks involve feeling bored or losing time due to the interviews. Other risk may include breach of confidentiality. Likely, there will be no more risks than a normal day of life.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they 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.

Benefits

This study is not designed to benefit you directly. This study is designed to learn more about ways to promote caregiver mastery online. The study results may be used to help others in the future.

Compensation

You will get $20 for each completed interview. If you do not finish the study, you will be paid for the interviews you have completed. You will receive $80 total, if you complete all study interviews.

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 funder(s), the Emory Institutional Review Board, the Emory Office of 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.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data [and specimens] from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Contact Information

Contact Dr. Fayron Epps at [redacted]:

- if you have any questions about this study or your part in it,
- 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.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print/type** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights.

Name of Subject

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**