Informed Consent Form

Title: Mastering the Challenges of Dementia Family Caregiving in a Time of COVID-19: An Online Course

NCT Number: NCT04939714

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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 100 people who are being studied, at Emory.

Why is this study being done?
This study is being done to answer the question: How acceptable, useful, and effective is a fully online, self-administered course on Caregiving During Crisis in preparing family and friend caregivers who provided unpaid care for persons living with Alzheimer's and similar dementia disorders (PLWD) to deal with providing care in a crisis situation like COVID-19? You are being asked to be in this research study because you are 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 five months. The researchers will ask you to do the following: participate immediately or after a 3-month wait in the online course and take part in three research interviews and, possibly, in a focus group and/or an 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 breach in confidentiality and transient emotional discomfort. A full list of expected risks is provided 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 researcher 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

Title: Mastering the Challenges of Dementia Family Caregiving in a Time of COVID-19: An Online Course

Principal Investigator: Carolyn Clevenger, DNP, APRN; Kenneth Hepburn, PhD, 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 test an on-line (internet-based) program that provides information and education to informal caregivers (family and friends) of persons with Alzheimer's disease (or related illnesses). The program is meant to enhance caregivers' knowledge and skills for providing care during extreme crisis situations such as the Novel Coronavirus (COVID-19) pandemic. You are being asked to take part in this study because you are a caregiver of a person living with dementia.

The program is an online education course. The course has three main sections. The first provides information about the transmission of viral diseases, like COVID-19, and about ways to keep you and the person for whom you provide care as safe as possible in crises like the current pandemic. The second section provides information about how to be more effective when using the healthcare system either for yourself or your person and how to prepare for using the healthcare system in times of crises like the current pandemic. The third section of the course provides information about ways to more effectively guide the days of a person living with Alzheimer's or related illnesses.

The research study is meant to answer three kinds of questions. The first kind of question is whether those who take part in the program find it appropriate (that is: does it address the issue it is meant to address?), acceptable (that is: is the material presented in a manner that speaks to you clearly and respectfully as a caregiver?), and usable (that is: is the course easy to use?). The second question the study is meant to address is whether the program helps caregivers to feel more competent and confident in providing care during a time of crisis and does it help caregivers feel less burdened and distressed in the conduct of their caregiving. The third question the study will address is: How can we improve the course? We hope to learn from caregivers who take part in the course the ways in which it can be strengthened and enhanced to better meet the needs of caregivers.

Procedures

If you are eligible and want to be part of the study, you will be asked to do the following:

Research Interviews: We will ask all participants to take part in three interviews, conducted by phone or videoconference, over a period of about five months. In the first of these, we will ask you to provide information about yourself, the person for whom you are providing care, and other background information about your situation. In all of the interviews we will ask you to respond to questions from several standard research questionnaires. These questionnaires will ask about your emotional well-being, in areas such as anxiety, stress, burden, and depression; they will ask about the care you are providing and your feelings about providing care. Each interview should take no longer than 30 minutes.

Semi-structured Interviews. After you have completed the third research interview, we may ask you to participate in a one-on-one conversation, by phone or videoconference, with one of the investigators. We will invite about 20% of those taking part in the study to join in these interviews. These interviews are meant to serve two purposes. The first purpose is to provide us with a more in-depth view of how caregivers felt about the course and the ways it might have benefited them or not. The second purpose is to learn from caregivers how we might improve and strengthen the course. The interviews are meant to be like conversations, and we will have a few standard questions (for example: "Can you tell me your overall impression of the course") that are meant to start those conversations. We expect these interviews will take 45-60 minutes.

Focus Groups. We will invite 16-20 individuals to take part in 2 focus one-hour groups (of 8-10 persons each) prior to their beginning the course. The purpose of these focus groups is to learn about caregivers' experiences as caregivers during COVID-19 and as companions of persons living with dementia as those persons may have used the healthcare system. The focus groups will be conducted virtually, using a videoconferencing platform like Zoom, and will be led by one of the study investigators. Information from these focus groups is expected to assist us in strengthening and further developing the course following the completion of the study.

Course Participation. The study is being conducted as a randomized wait-list controlled trial. In this kind of study, all who agree to participate will be enrolled in the program. The study's randomized design means that half of those whom we recruit will be asked to take part in the program immediately and the other half will be asked to wait for a period of approximately 3 months before taking part. Following the first research interview, participants will be asked to take part in the 6-8 week course, either immediately or after the second research interview, approximately 10 weeks after the first interview.

The course is designed to be completed in 6-8 weeks, but it is completely self-paced, so you can take part in it on your own schedule, any time day or night, and you can start and pause it on your own schedule. There will be other caregivers who are enrolled in the course at the same time, but you and they will never meet, and you will not learn each other's identities; there is no online group activity. The course does include exercises, such as reflections on or responses to the instructional material. Your responses will be shared anonymously with a small group of other participants, and you will likewise receive the responses and reflections of a small group of other participants. The sharing is a deliberate part of the program; it is designed to enable individual participants to see how others who are in similar situations might think about or handle challenges they are facing as "COVID caregivers." A faculty member from the Nell Hodgson Woodruff School of Nursing will be moderating the program. The moderator will be reviewing participants' responses and may provide feedback on them.

If you agree to take part in the study, regardless of whether you are randomly assigned to immediate or wait-list, you can expect to be involved in the study for approximately five months.

Risks and Discomforts

There is little risk to you for participating in this study. The major risks may involve feeling bored or losing time due to the interviews and possible transient emotional upset due to the subject matter of the course or the interviews. The

topics covered in the course and in the research interviews and in the semi-structured interviews and/or focus groups that you might be invited to take part in will cover material that might produce transient emotional reactions. Caring for a person living with dementia can be challenging, and just being with a person whose life is so profoundly affected by an illness like Alzheimer's can be emotionally difficult. The interviews and course may tap into these feelings. Other risk may include breach of confidentiality. Likely, there will be no more risks than a normal day of life.

The person who will conduct the research interviews has been trained to be alert to the possibility that some questions asked in the interview may be upsetting to participants. Should such an event occur, the interviewer will ask if you would like to take a break or reschedule the interview for another time. You are also free to refuse to answer any questions that are raised during the interviews. The research investigators who will conduct the semi-structured interviews and the focus groups are researchers with extensive experience working with caregivers. They, too, will be alert to situations of emotional upset and will offer time to move away from any sensitive topics.

You will be assigned a study ID number, and that number will be the only form of identification on any research document, such as the completed research interview. Only the principal investigator (Dr. Clevenger) will have the separate master sheet that links your name to the ID number, and she will keep that separate from all other research materials in a locked file in her locked office.

The semi-structured interviews and the focus groups will be audio-recorded so that they can be transcribed for study purposes. The transcriptions will only identify you by your study ID, and the audio recordings will be deleted at study's end.

There is one other fact about which you should be aware. Because the person for whom you are providing care is considered a vulnerable adult, the research team is under a legal and ethical obligation to report to adult protective services any observed instances of abuse or neglect of the person.

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 not be paid to take part in the study. However, in appreciation for the time involved, we will offer you a $25.00 gift card for each interview in which you participate.

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 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 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. Carolyn Clevenger 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**