Informed Consent Form

TITLE: Caregiving While Black-LIVE: Empowering Black Dementia Caregivers to Navigate Care

NCT NUMBER: NCT06605391

IRB APPROVAL DATE: April 17, 2023

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 40 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-guided course on managing the complexities of caregiving in a pandemic while addressing the cultural reality of being a Black American? You are being asked to be in this research study because you are a 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 twelve months. The researchers will ask you to take part in the Caregiving While Black course, which will be delivered online. Although the course is self-paced you will be asked to complete the course over an 8-week period. The researcher may also ask you to partake in a focus group interview and/or individual interviews via telephone or using a videoconferencing platform to further discuss the course.

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 of 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. 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 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: Caregiving While Black-LIVE: Empowering Black Dementia Caregivers to Navigate Care

IRB #: 00005946

Principal Investigator: Fayron Epps, PhD, RN

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.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

What is the purpose of this study?
The overall purpose of this project is to develop and test an online and face-to-face education program designed to enhance the mastery of Black American caregivers to provide care to family members or friends living with a dementia illness.

What will you be asked to do?
Phase 1:
We will invite 24-30 individuals to take part in 3 focus 90-minute groups (of 8-10 people each) to assist in course design (i.e., design studio exercises). The purpose of these focus groups is to have caregivers participate in designing the Caregiving While Black:LIVE course. 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 help us strengthen and further develop the course after the study. Sessions will last approximately 90 minutes and will be audio-recorded.

Phase 2:
Research Interviews: Participants will be asked a series of questions in a baseline interview, and then will be asked to partake in the course during an 8-week period. At 3- and 6-month post-enrollment you will be interviewed once again. In all 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

60 minutes. You may also be asked to partake in an evaluation interview via audiotaped phone or video semi-structured interviews.

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 (audiotaped), with one of the investigators. 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.

Who owns your study data and samples?

If you join this study, you will be donating your data. You will not be paid if your data are used to make a new product. If you leave the study, the data that were already collected may be still be used for this study.

What are the possible risks and discomforts?

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

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?

You may not benefit from joining the study. This study is designed to learn more about important activities for persons with memory loss and their family caregivers. The study results may be used to help others in the future.

Will you be paid for your time and effort?

You will get $ 40 for each completed study interview, for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get $160 total, if you complete all study visits. You may be asked to fill out a tax form with your Social Security or Taxpayer Identification Number depending on the amount and method of payment. If your payment will be sent to your house in the mail and could be seen by others in your household you can choose not to be compensated. You can decline payment if you are concerned about confidentiality, or you can talk to the study team if there are other ways to be compensated.

What are your other options?

If you choose not to join this study, you can get education outside of this study. Feel free to visit the Alzheimer's Association (www.alz.org) to The lead researcher will discuss these with you. You do not have to be in this study to receive education.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study 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

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

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

Costs

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

Withdrawal from the Study

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

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the last planned study interview, the researchers may ask you to complete some of the final steps such as surveys or questionnaires as applicable.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

These are some reasons why the researchers may take you out of the study:

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

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Dr. Fayron Epps at [redacted]

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

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**