Informed Consent Form

TITLE: Creating a Faith-Based Toolbox for African Americans Living With Moderate and Severe Dementia

NCT NUMBER: NCT04325204

IRB APPROVAL DATE: November 15, 2021

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 75 people who are being studied, at Emory and elsewhere.

Why is this study being done?

This study is being done to answer the question: What faith-based home activities are useful for African American adults with moderate and severe dementia and their caregivers. You are being asked to be in this research study because you are a person living with moderate or severe 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 in faith-based activities three times per week for twelve weeks. The researchers will ask you to do the following: complete these faith activities with your family member. All of these procedures will be paid for by the study.

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. There also may be a 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.

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

Costs

There is no cost associated with 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

Phase 2: Person living with Dementia

Title: Creating a Faith-Based Toolbox for African Americans living with Moderate and Severe Dementia

Principal Investigator: Fayron Epps, PhD, RN, Nell Hodgson Woodruff School of Nursing

Funding Source: National Institute on Aging/NIA (pending)

If you are a legally authorized representative who is signing the Informed Consent Form on behalf of the participant, the pronouns "you" and "your" should be read as referring to the participant rather than legally authorized representative.

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 create and test faith-based activities that might be useful for African American adults with moderate and severe dementia and their caregivers. A total of 60 people will take part in Phase 2 of this study, 30 people with moderate and severe dementia and 30 family caregivers.

Procedures

If you decide to take part in this study, you will take complete faith-based activities. You will participate in faith-based activities three times per week for six weeks (9 hours). Your caregiver will also provide us with some of your personal information such as age, gender, and information about difficult behaviors

- You will complete 3 faith activities a week for 6 weeks.
- You will complete these faith activities with your family member.
- Your family member will provide information about you.

Risks and Discomforts

In this study, you will not have any more risks than you would in a normal day of life. No harm to you is expected from this study. But if you believe you have been harmed, contact the research team as soon as you can. Emory University and the research team have not set aside funds to give you money for any harm that may occur. Other risk may include breach of confidentiality.

Benefits

This study is not designed to benefit you directly. This study is designed to learn more about faith activities that may help African American adults with memory loss. The study results may be used to help others in the future.

Compensation

You will not be offered payment for being in this study.

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 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. 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** 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**

Signature of Legally Authorized Representative **Date** **Time**

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

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