Informed Consent Form

Title: Faith-Based African American cancer Survivorship Storytelling: A culturally relevant intervention to alleviate psychological stress

NCT Number: NCT03082612

IRB Approval Date: December 21, 2021

Emory University Nell Hodgson School of Nursing
Oral Consent Script
For a Research Study

Study Title: Faith-Based African American cancer Survivorship Storytelling: A culturally relevant intervention to alleviate psychological stress.

IRB #: 00093110

Principal Investigator: Jill B. Hamilton, PhD, RN, FAAN; Associate Professor; Nell Hodgson Woodruff School of Nursing; Emory University

Funding Source: NIH/National Institute of Minority Health and Health Disparities

Introduction and Study Overview

Thank you for your interest in our research study that is aimed at assessing psychological stress associated with cancer diagnoses. We would like to tell you everything you need to think about before you decide whether or not to join 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.

The purpose of this research study is to explore those things that make a diagnosis of cancer upsetting or stressful and to also find out if seeing videos of other African American cancer survivors talking about their experience and listening to the religious songs and texts they have used will help you to relieve your stress. What we learn from this research might help other African American cancer patients and their family members during a diagnosis and treatment for cancer.
The study is funded by NIH/National Institute of Minority Health and Health Disparities.

If you decide to participate in this research study, you will be asked to complete a total of 5 interviews that may last approximately 30 – 45 minutes. You will also be asked to watch a brief series of videos of other African Americans who have had treatment for cancer. These stories are told by other African American cancer survivors telling their stories of how they found hope, comfort, and strength during treatment through a religious song. Participants will be asked to complete a 6th optional, open-ended interview to further explore sources of distress and strategies used to relieve that stress.

If you decide to be in this study, you will be interviewed by telephone or zoom at a time convenient for you. During these interviews, you will be asked questions about how you have been feeling since being diagnosed with cancer. You may also be asked to talk about how seeing or hearing stories from other African American cancer survivors makes you feel. We will also collect other information about you such as your age, where you grew up, and times when you might use a religious song during treatment. Some parts of your interview will be audio recorded and later transcribed.

There are no foreseeable risks to you for participating in this study. If there is a deviation from research study protocol or procedures, a possible risk is a breach of confidentiality. Additionally, talking about aspects of your illness may make you sad. However, you may refuse to answer any questions or stop the interview at any time.

Research is designed to benefit society by gaining new knowledge. There is little chance you will personally benefit from being in this research study. However, there may be benefit to you from talking about your cancer experience and sharing your story with others.

There are no costs to you for participating in this study. You will be receiving $30.00 value for each study interview. You may be asked to participate in a total of 5 interviews (1 additional, optional interview) for which you will receive a total of $180 if all 6 interviews are completed.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents. 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 Food and Drug Administration, the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, 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.

We will disclose your information when required to do so by law in the case of reporting child abuse or elder abuse, in addition to subpoenas or court orders.

The investigators have obtained a Certificate of Confidentiality for this study. If Emory received a subpoena for study records that identify you, we would say no, and the Certificate gives us this authority. The Certificate does not prevent you or someone other than you from making disclosing your information. The Certificate also does not prevent Emory from releasing information about you:

- Information to state public health offices about certain infectious diseases
- Information to law officials if child abuse has taken place
- Information Emory gives to prevent immediate harm to you or others
- Information Emory gives to the study sponsor as part of the research

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.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Contact Information

If you have any questions about your rights as a research participant, or if you think you have not been treated fairly, you may call the Emory Institutional Review Board (IRB) at 404-712-0720 or 877-503-9797 or irb@emory.edu.

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu. We will continue to collect information about you until the end of the study unless you tell us that you have changed your mind.

If you change your mind and don't want your information used for the study anymore, you can contact the PI [redacted] at [redacted] or [redacted]. Just remember, if we have already used your information for the study, the use of that information cannot be cancelled.

Consent

Do you have any questions about anything I just said? Were there any parts that seemed unclear?

Do you agree to take part in the study?

Participant agrees to participate: Yes No

If Yes:

_____

Name of Participant

_____ _____

Signature of Person Conducting Informed Consent Discussion Date Time

_____

Name of Person Conducting Informed Consent Discussion