Developing and Pilot Testing Culturally Based Educational Videos for Puerto Rican and African American Home Hospice Caregivers

NCT06024278

Consent Form approval: 09/19/2023-07/10/2024

Consent to be Part of a Research Study

Title of the Project: Developing and pilot testing culturally based educational videos for Puerto Rican and African American home hospice caregivers.

Principal Investigator: Veerawat Phongtankuel, MD, MS, Weill Cornell Medicine
Study Sponsor: National Institute on Aging

Invitation to be Part of a Research Study

You are invited to participate in a research study. In order to participate, you must be a family caregiver who identify themselves as African American or Puerto Rican, English and/or Spanish speaking, and 18 year of age or older. Taking part in this research project is voluntary.

Important Information about the Research Study

Things you should know:

- The purpose of the study is to pilot caregiver videos aimed to educate (Puerto Rican/African American) caregivers about symptom related issues in home hospice care. Our goal is to gather information and feedback from caregivers like yourself on the impact of these videos. If you choose to participate, you will be asked to take part in a one-time interview via video. This will take approximately 1 hour of your time.
- Risks or discomforts from this research include answering questions or watching video topics that may be sensitive to you. You can choose to stop participating at any time.
- We cannot guarantee that you will receive any benefits from this study. However, we will compensate you with a $50 gift card for your time.
- Taking part in this research project is voluntary. You don't have to participate and you can stop at any time.

Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

What is the study about and why are we doing it?

The purpose of the study is pilot caregiver videos aimed to educate (Puerto Rican/African American) caregivers about symptom related issues in home hospice care. Our goal is to gather information and feedback from caregivers like yourself on the impact of these videos.

What will happen if you take part in this study?

If you agree to take part in this study, we will schedule a time that is convenient for you to meet via video. We will initially ask you a few questions. Afterwards, we will show you 4 videos on symptom related issues in home hospice care and follow that with another series of questions. The study should take 1-hour of your time and you will receive a $50 gift certificate for your participation.

Your data will not be linked to any other data.

How could you benefit from this study?

Although you will not directly benefit from being in this study, others might benefit because the aim of the project is to develop educational videos for future home hospice caregivers.

What risks might result from being in this study?

There is minimal risk you might experience from being in this study. You may feel uncomfortable answering certain questions or watching the videos. If this occurs, please let the research member know and you can choose to stop participating at any time. There is always a risk that the data collected may be stolen or breached. However, we have put into place safeguards to minimize this risk.

How will we protect your information?
We plan to publish the results of this study. To protect your privacy, we will not include any information that could directly identify you.

We will protect the confidentiality of your research records by storing your data on a password protected computer under a secure server. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**.**

It is possible that other people may need to see the information we collect about you. These people work for the Visiting Nurse Service of New York, the National Institute on Aging, and government offices that are responsible for making sure the research is done safely and properly.

A description of this study will be posted on a public website, http://ClinicalTrials.gov, and summary results of this study will be posted on this website at the conclusion of the research, as required by the National Institutes of Health (NIH), the study sponsor. No information that can identify you will be posted.

What will happen to the information we collect about you after the study is over?
We will not keep your research data to use for future research or other purpose. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you.

How will we compensate you for being part of the study?
You will receive a $50 gift certificate for your participation in this study. You will still receive compensation even if you withdraw from the research before the end of the study.

Your Participation in this Study is Voluntary
It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed, we will erase any data at your request.

Contact Information for the Study Team and Questions about the Research
If you have questions about this research, you may contact Dr. Veerawat Phongtankuel, 525 East 68th street Box 39, New York, NY 10065, 212-746-7000 or Dr. Dulce Cruz-Oliver, N 600 Wolfe street Blalock suite 359, Baltimore, MD 21287, 4109558305.

Contact Information for Questions about Your Rights as a Research Participant
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:
VNS Health IRBPhone: (212) 609-5766
Email: lori.king@vnshealth.org
or
Johns Hopkins IRB
Phone: (410) 502-2092
Email: jhmeirb@jhmi.edu

Certificate of Confidentiality (CoC)

This research holds a Certificate of Confidentiality from the National Institutes of Health.

What is a Certificate of Confidentiality?

With this Certificate, the researchers may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. This study is protected by a Certificate of Confidentiality that helps keep your information private when stored in the U.S.

When are the researchers allowed by the CoC policy to disclose my information?

- If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

- The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

- If you have consented to the disclosure, including for your medical treatment. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

- If it is used for other scientific research, as allowed by federal regulations protecting research subjects.

When may the researchers disclose my research information for this study?

If the National Institute on Aging, the agency funding this research, requests information to audit or evaluate our procedures; or if we must disclose information in order to meet the requirements of the federal Food and Drug Administration (FDA).

Your Consent

I authorize the use of my personal health information in connection with the Research Project.

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time