Piloting a Multi-component Technology-based Care Intervention to Address Patient Symptoms in Home Hospice

NCT04243538

Consent form approval: 9/5/2024 – 9/4/2025

Aim 3 – Oral consent form

Oral Consent Form for Research Study

Project Title: Developing and piloting a multi-component technology-based care intervention to address patient symptoms and caregiver burden in home hospice.

VNSNY IRB #: 1416823

WHY ARE YOU DOING THIS STUDY?
You are invited to participate in a study that will test a technology-based care intervention called I-HoME. I-HoME uses video visits with a nurse and educational videos. This intervention will last up to 6 weeks. Researchers from Weill Cornell and VNS Health will collect data during the study to learn how to best use this program in home hospice care. You were asked to join this study because you are a caregiver to someone who is receiving home hospice care.

WHAT HAPPENS IF I SAY YES, I WANT TO BE IN THIS STUDY?
If you decide to participate, a research member from Weill Cornell and VNS Health will explain the I-HoME program and then ask you survey questions. This initial process will last about 30 minutes. After this initial call, you will be mailed a tablet and a user-guide to be able to use the I-HoME program for up to 6 weeks. You also will be mailed a gift card for your participation.

After the initial call, you will be called once a week for up to 6 survey interviews. A research member will call you to complete an interview with you which will last 15 to 30 minutes. During each interview, we will ask you questions about the feasibility of the intervention, symptoms, burden, depression, and anxiety. We will also collect information from the medical record at VNS Health as part of the study. This information will include the services used while receiving hospice care.

Your participation in this study will not impact the plan of care from hospice services at VNS Health.

ARE THERE ANY RISK TO BEING IN THE STUDY?
Your participation in the study involves minimal risks. During the interviews and assessments, we will be asking you for some personal information and asking questions about how you feel. You may feel uncomfortable answering certain questions. In addition, you may find the I-HoME intervention not useful or beneficial. If either of these cases occur, please notify a research member. This study is entirely voluntary, and you can choose to stop participating at any time. The only people who have access to the information will be the study team members. The study team will do everything we can to protect your private information. All of your private information will be in secure files and computers that have limited access.

ARE THERE ANY BENEFITS TO BEING IN THE STUDY?
It is possible you may not receive any benefits from participating in this program, but your participation is particularly important to the success of this study. The information that you give us will help us to continue to create better programs for others like you. You will receive a $50 gift card for this initial call and $25 for each phone survey that you participate in. There is no payment for meeting with the study nurse. You will also receive a tablet with internet service for the duration of the study.

WHO WILL SEE THE INFORMATION ABOUT MYSELF?
We will do everything we can to keep your information private. Sometimes, other people may need to see the information. For example, if we found your safety or health was at risk, we would have to follow through to be sure that you are protected. The study investigator may also share a copy of this consent form and/or records that identify you with the following people: The VNS Health Institutional Review Board, Weill Cornell Medicine Institutional Review Board, the National Institutes of Health, the Office of Human Research Protections, or other government agencies.

WHAT HAPPENS IF I SAY NO, I DO NOT WANT TO BE IN THE STUDY?
Your participation in this study is completely voluntary. If you do not want to participate, you can refuse to provide oral consent. Your decision whether to participate will not impact care with Weill Cornell or VNS Health.

WHAT IF I HAVE QUESTIONS?

If you have any questions, please ask us. If you have any additional questions later, Dr. Veerawat Phongtankuel (525 East 68th street Box 39, New York, NY 10065, 212-746-7000) will be happy to answer them.

If you have any questions regarding your rights as a research subject or concerning a research related injury, please call (Margaret McDonald 212-609-5761).

You will be mailed/emailed a copy of this form to keep.

WHAT SHOULD I DO IF I WANT TO BE IN THE STUDY?
If you want to be in the study, please provide verbal consent near the end of our call. Your verbal consent indicates that you understand the information provided above and have decided to participate in the study.

WHAT SHOULD I DO IF I DECIDE I NO LONGER WISH TO BE IN THE STUDY?
If you agree to take part in this study now, you may also tell us you want to leave the study at any time, for whatever reason.

STATEMENT OF VERBAL CONSENT
By providing verbal consent, I agree to participate in this study and affirm that I am 18 years or older. I understand that I may stop or withdraw from this program at any time. Also, the study managers may withdraw me from this study as they see fit.

_____ _____
Name of participant Date

RESEARCHER'S STATEMENT
I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____ _____ _____
Signature of person obtaining consent Print name of person Date