Adapting and implementing the I-HoME intervention in caregivers of patients with ADRD

NCT 06488157

Consent Form Approved on 6/5/2023, non-expiring

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC

WEILL CORNELL MEDICAL COLLEGE
SUBJECT INFORMATION AND INFORMED CONSENT FORM
AIM 2 – Caregivers

Protocol Title: Adapting and implementing the I-HoME intervention in caregivers of patients with ADRD
Protocol #: 23-01025643
Sponsor: National Institute on Aging
Principal Investigator: Veerawat Phongtankuel, MD, MS
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Key Information Statement

The purpose of this study is to evaluate the **I**mproving **Ho**me hospice **M**anagement of **E**nd-of-life issues through technology (I-HoME) intervention for caregivers with advanced dementia patients. Study subjects will complete up to 6 telehealth visits with a nurse practitioner to help address symptoms of their family member with advanced dementia and related dementias (ADRD). Subjects will also complete up to 7 weekly phone survey assessments with a research assistant. There are total 7 study visits. Participation is completely voluntary. There is the risk of loss of confidentiality of your medical and personal information collected for this study.

If you are interested in learning more about this study, please continue to read below, where you will find additional information related to this study such as the risks, benefits, procedures, alternatives, and contact information.

INFORMED CONSENT FORM

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS
The National Institute on Aging, the sponsor of this study, is providing funds to WCM/NYPH for conducting this research study.

PURPOSE OF THE STUDY
The purpose of this study is to evaluate the feasibility and effectiveness of an experimental intervention called **I**mproving **Ho**me hospice **M**anagement of **E**nd-of-life issues through technology (I-HoME).

NUMBER OF SUBJECTS AND LENGTH OF STUDY PARTICIPATION
About 90 subjects are expected to participate in this study at 1 research sites in the United States. About 30 subjects will participate in this part of the study (Aim 2).

Your participation in this study is expected to last up to 12 months.

STUDY PROCEDURES

If you decide to participate, a study team member will explain the I-HoME program and 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 the duration of the study. You also will be mailed a gift card for your participation. After the initial call, you will be called at a regular monthly basis for up to 6 months. 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 the Center on Aging or the House Call program at Weill Cornell Medicine as part of the study. After each visit, a summary of the plan will be relayed to the patient's care team at the Center on Aging and/or the House Call program. Your participation in this study will not impact the care you receive from either provider.

RISKS AND DISCOMFORTS

There are risks to taking part in any research study. The risks associated with this study are minimal. There are no risks of physical injury related to study activities. The study team member will ask you questions related to your experience with the intervention, your mood, and the symptoms your patient is experiencing. You have the right to not answer a question or stop the survey at any time.

Every effort will be made to protect your privacy. No personal health information or private identifiable information will be linked to study data.

NEW INFORMATION

You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

Clinically Relevant Research Results

The overall results of this study may or may not be available to you at the end of the study. The study doctor will also explain if and when you will receive individual research results that may have clinical significance.

BENEFITS

There is no guarantee that your/your care recipient's condition will improve as a result of your participation in this study. It may stay the same or worsen. However, the information learned from this study may help other caregivers of people with advanced dementia and related dementias in the future.

ALTERNATIVES TO STUDY PARTICIPATION

Your alternative to being in this study is to not take part in this study.

COSTS OF PARTICIPATION

The sponsor of this study will provide the study device (tablet) to you at no charge. There are no costs to you for participating in this study.

You and/or your insurance company will be responsible for the costs of all items and services during the research study, which you would have received for your condition if you were not enrolled in this research study and/or that your physician believes are medically necessary to treat you. You should discuss possible costs of study participation with the study staff and/or your insurance company.

REIMBURSEMENT
You will receive $25 for each completed feedback interview that you complete during the study during 5 timepoints during the study. If you leave the study early, you will be reimbursed only for visits you complete. You will receive this in the form of participant choice gift cards (e.g., Amazon, American Express, Target).

Tax law may require the payer (e.g., research institution or third party) to report the amount of payment you receive from that payer to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting will take place if you receive $600 or more from the payer in a calendar year. You would be responsible for paying the taxes on the payment you received from the study.

COMPENSATION FOR INJURY
Because this study involves only the sharing of information and requires no specific procedures, tests, or treatments, no research-related injuries are expected. No other compensation will be offered by the sponsor or WCM/NYPH or Biomedical Research Alliance of New York, including for things such as lost wages or discomfort. You are not waiving any legal right to seek additional compensation through the courts by signing this form.

CONFIDENTIALITY
To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the WCM Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION
Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history

- Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The WCM Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards
- Health insurers and payers
- Other individuals and organizations that analyze or use your information in connection with these research activities, including laboratories, contract research organization and study sites (if you transfer to another study site)

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue

being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Collection of Identifiable Private Information or Identifiable Biospecimens:

- Your information and biospecimens collected as part of this research study, even if identifiers are removed, will not be used or distributed for future research studies.

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the agencies responsible for protecting your rights.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the study doctor.

Your participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the sponsor, the FDA and other regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you need treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to

return to the study doctor's office for a final study visit for your safety.

CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS
If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Veerawat Phongtankuel at 212-746-1501.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research. The IRB is a committee that reviews research studies to help protect the rights and welfare of study subjects.

STATEMENT OF CONSENT - SIGNATURES
By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

Subject: Name (Print)	Signature	Date

Person Obtaining Consent: Name (Print)	Signature	Date