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

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Confidentiality Statement

This document is confidential and is to be distributed for review only to investigators, potential investigators, consultants, study staff, and applicable independent ethics committees or institutional review boards. The contents of this document shall not be disclosed to others without written authorization from WCM.

List of Abbreviations

ADRD	Alzheimer's Disease and related dementia
CFR	Code of Federal Regulations
CTSC	Clinical Translational Science Center
FDA	Food and Drug Administration
FAST	Functional Assessment Staging Tool
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
I-HoME	Improving Home hospice Management of End-of-life issues through technology
ICF	Informed Consent Form
IRB	Institutional Review Board
PHI	Protected Health Information
PI	Principal Investigator
REDCap	Research Electronic Data Capture
WCM	Weill Cornell Medicine

1. Protocol Summary

Full Title: Adapting and implementing the Improving Home hospice Management of End-of-life issues through technology (I-HoME) intervention in caregivers of patients with Alzheimer's Disease and related dementias (ADRD).

Short Title:	I-HoME and ADRD
Principal Investigator:	Veerawat Phongtankuel, MD, MS
Study Description:	Aim 1 of the protocol is to adapt the I-HoME intervention for caregivers of ADRD patients with advanced illness by leveraging stakeholder input through interviews with providers (n=30) and caregivers (n=30) of ADRD patients. Using an iterative user-centered design approach, the data collected will inform adaption of the I-HoME manual, protocol, and data collection instruments to address the care needs of patients with ADRD and their caregivers. Aim 2 of the proposal is to pilot test the adapted I-HoME intervention with family caregivers (n=30) of ADRD patients with advanced illness. Data will be collected regarding intervention feasibility and acceptability. Secondary measures will consist of ADRD symptom assessment tools, caregiver burden, caregiver anxiety and depression scores, and caregiver satisfaction.
Sample Size:	N = 90
Enrollment:	This study will enroll 90 subjects and screen up to 300 subjects.
Study Population:	Healthcare professionals (Aim 1 only) and adult caregivers ≥18 years old and <105 years old who provide care to a patient with advanced ADRD (Aims 1 and 2).
Enrollment Period:	2 years
Study Design:	Aim 1 will implement an iterative user-centered design approach through qualitative interviews. The data collected will inform adaption of the I-HoME manual, protocol, and data collection instruments to address the care needs of patients with ADRD and their caregivers. Aim 2 will be a pilot study looking at feasibility and acceptability of implementing the I-HoME intervention for caregivers of ADRD patients.
Description of Sites Facilities Enrolling Participants:	Participants will be recruited from Weill Cornell's Center on Aging (Aims 1 and 2) and from the hospice medical director website (Aim 1 only).
Study Duration:	2/1/2025
Participant Duration:	Aim 1 – 4 months Aim 2 - 1 year
Primary Objective:	Aim 1 - to adapt the I-HoME intervention for caregivers of ADRD patients with advanced illness Aim 2 - To evaluate the feasibility and acceptability of implementing the I-HoME intervention for caregivers of ADRD patients.
Secondary Objectives:	N/A
Exploratory Objectives:	N/A

Primary Endpoints: Feasibility outcomes are measured by examining the percentage of caregiver participants who enroll in the study and the percentage of caregiver participants who complete the telehealth visits.

Secondary Endpoints: Secondary endpoints will consist of ADRD symptom assessment tools (Doloplus-2 scale and behavioral and psychosocial symptoms of dementia (BPSD) scale), caregiver burden (Zarit Burden Interview – short version), and caregiver anxiety (General Anxiety Disorder-7 scale) and depression (Patient Health Questionnaire-8 scale) scores.

1.1 Study Objectives

1.1.1 Objectives

Aim 1: To adapt the I-HoME intervention for caregivers of ADRD patients with advanced illness by leveraging stakeholder input through interviews with providers (n=30) and caregivers (n=30) of ADRD patients.

Aim 2: To pilot test the adapted I-HoME intervention with family caregivers (n=30) of ADRD patients with advanced illness.

1.1.2 Hypotheses / Research Questions

We hypothesize that implementing the adapted I-HoME intervention will be feasible and acceptable to participants.

2. Background and Significance

Use of palliative care services in the US has risen steadily over the past few decades, with over 80% of hospitals having a palliative care team[1] and over 50% of Medicare decedents receiving hospice services.[2] In the 1980s, most palliative care services were delivered to cancer patients.[3] However, there has been a marked shift in the types of patients receiving these services today. In particular, the number of patients with Alzheimer's Disease and Related Dementias (ADRD) who need and/or receive End-of-Life (EoL) care has increased steadily. Dementia is now the fifth leading cause of death[4] among older adults, and of all patients receiving hospice care, 45% have a primary or secondary dementia diagnosis.[5] Yet, research focused on developing and testing services and models to best meet the palliative care needs of ADRD patients and their caregivers remains modest. As a result, multiple organizations have called for research to improve palliative care in affected patients and their caregivers.[6–8]

ADRD patients with advanced illness present unique challenges for care provision when compared to patients with non-dementing terminal illnesses. One notable challenge is an inability to clearly communicate their symptoms or care needs. Patients are also more likely to exhibit behavioral and psychosocial symptoms of dementia (BPSD).[9] These issues pose a challenge for caregivers and providers with respect to assessing and managing symptoms and providing optimal palliative care. Furthermore, caregivers of patients with (vs. without) ADRD that are approaching the EoL are more likely to suffer from depression, anxiety, and poor physical health.[10–12] Therefore, supporting family caregivers of ADRD patients with advanced illness who need palliative/EoL care services is essential for their well-being and for the well-being of affected patients.[13]

To date, little research has focused on finding solutions to improve palliative/EoL care outcomes among ADRD patients with advanced illness and their caregivers. In a recent systematic review[6] examining ADRD patients receiving hospice care, the authors identified only 10 intervention studies, with 3 reporting ambiguous objectives or equivocal outcomes. In addition, many providers lack formal training in how to deliver palliative care to ADRD patients[14] and evidence-based practices are lacking.[15] Given the dearth of high quality evidenced-based solutions, ADRD patients with advanced illness and their caregivers may receive suboptimal palliative care, leading to unwanted outcomes such as burdensome care transitions[16,17], especially among African American and Latinx patients.[17]

The **I**mproving **Ho**me hospice **M**anagement of **E**nd-of-life issues through technology (I-HoME) intervention is a caregiver-directed intervention that supplements existing care with video visits and education provided by a palliative trained nurse practitioner. Visits with a nurse practitioner focus on assessing and treating distressing

patient symptoms and supporting caregivers through education around symptom management. However, I-HoME was not designed to account for the special care needs and challenges of ADRD patients. This protocol aims to adapt the I-HoME intervention for caregivers of ADRD patients with advanced illness.

3. Study Design and Methods

3.1 Overall Design

Aim 1
A user-centered design approach will be incorporated and involve healthcare providers and caregivers of patients with ADRD.
For the first phase of Aim 1, the study will recruit (n=30) geriatricians and palliative care providers at Weill Cornell Medicine along with hospice medical directors from a national registry. In addition, caregivers (n=30) of ADRD patients with advanced illness will be recruited from Weill Cornell Medicine. Data collected in this phase will be used to adapt the current version of the I-HoME intervention.
For the second phase of Aim 1, as part of the iterative user-centered design process, participants from the first phase will be recruited to provide additional feedback *(see Follow-up Questionnaires with submitted data collection material)* on the adapted version of I-HoME to further refine the intervention.

Study population

Healthcare providers will be recruited from Weill Cornell Medicine and a hospice medical director website (hmdcb.org). Caregivers of ADRD patients will be recruited through referrals from providers at the Center on Aging and the House Call program at Weill Cornell Medicine.

Recruitment

For recruitment of healthcare providers, an email will be sent out to clinicians detailing the study. A member of the research team will follow up with interested participants and schedule a time to obtain informed consent and conduct an interview (in-person, virtually).

For recruitment of caregivers, the research team will obtain a list of potential caregiver participants based on the patient's dementia diagnosis from the electronic medical record. ADRD will be defined by using a modified list of the 22 International Classification of Diseases - Tenth Revision (ICD-10) diagnosis codes endorsed by the Centers for Medicare & Medicaid Services (CMS) for ADRD.[18] Once a list of patients is generated, the research team will then collaborate with the patient's provider at the Center on Aging and the House Call program to identify ADRD patients with advanced illness. The research team will use the Functional Assessment Staging Tool (FAST) scale for dementia to identify qualified participants. The research team will recruit caregivers of patients who are at a stage 7a-f on the FAST scale and have not had a medical complication over the past year.

Caregivers of patients that meet the study criteria will be contacted by phone and informed about the study. Interested caregivers will be scheduled to meet (in-person, virtually) where informed consent will be obtained and an interview will be administered. Participant inclusion criteria include, (1) age 18 years or older, (2) providing care to an ADRD patient with advanced illness, and (3) English speaking.

Participants recruited in Aim 1 will be compensated with a $75 gift certificate.

Data collection

An open-ended interview guide will be developed by the research team. The objectives of the interview for the first phase of Aim 1 are (1) to identify and understand the challenges (e.g., symptom management and care needs) in caring for ADRD patients and their caregivers; (2) to describe the current I-HoME protocol and intervention to participants; (3) to understand whether the current I-HoME intervention would be feasible and acceptable to caregivers of ADRD patients; and (4) to obtain input on adapting/modifying the current intervention to meet the symptom management and care needs of ADRD patients with advanced illness.

For the second phase of Aim 1, a subset of participants from the first phase will be asked to review the adapted I-HoME materials and provide feedback on the various intervention components which include the manual, protocol, content, and data collection instruments.

Aim 2

Aim 2 will be a pilot study examining the feasibility and acceptability of an adapted I-HoME intervention for caregivers of ADRD patients with advanced illness.

Study population

This study will recruit caregivers from the Center on Aging and the House Call program at Weill Cornell Medicine through referrals from providers.

Recruitment

Caregivers of ADRD patients with advanced illness will be identified from the medical records and screened by their provider. The caregiver will then be contacted by phone and informed about the study. Interested caregivers will be scheduled a time for an interview (virtually or in-person) where informed consent will be obtained. Participant inclusion criteria include, (1) age 18 years or older, (2) the family caregiver of the patient, (3) providing any sort of caregiving on a regular basis (at least weekly), (4) English speaking, and (5) have access to an electronic device with cellular data or Internet connection to access the telehealth platform.

After the caregiver is enrolled, a member of the research team will go over how to use their personal device to conduct video visits with the nurse practitioner. Software by Doxy.me[19] will be used to conduct HIPAA compliant video visits.

I-HoME intervention

The current I-HoME protocol involves video visits with a nurse practitioner for up to six visits to address symptom management and care needs. Nurse practitioners delivering the intervention go through a training session that familiarizes them with the I-HoME protocol. The protocol provides a framework for assessing/evaluating common patient symptoms and developing a treatment plan dependent upon the symptoms uncovered. After each visit, a summary of the treatment plan will be relayed to the patient's care team at the Center on Aging and/or the House Call program.

Data collection

Patient variables will be collected from the electronic medical record and are detailed in **Table 1**. Validated surveys and questions will be administered to the caregiver via phone by a research assistant. Caregivers will be assessed on the measures listed in **Table 2** at various timepoints in the intervention. Participants will be compensated with a $25 gift card each time they complete an initial, within study, and post-intervention survey phone call.

Table 1. Variables collected from the patient's electronic medical record

Demographic data	Post-intervention measures
Age	Number of office visits at Weill Cornell
Gender	Number of phone calls at Weill Cornell
Race/ethnicity	Hospitalization at Weill Cornell during intervention
ADRD diagnosis code	Enrolled into hospice care during intervention (yes/no)
Comorbidities	
Medications	
DNR/DNI status at time of enrollment	

Table 2. Measures administered at each time point to caregivers.

Baseline measures	Within study measures (After each visit)	Post-intervention measures (After final visit)
Age	BPSD (NPI[5])	BPSD (NPI2[5])
Gender	Pain (Doloplus-2[6])	Depression (PHQ-8[8])
Race/ethnicity	Burden (ZBI-short version[7])	Anxiety (GAD-7[9])
Religion/Spirituality	Depression (PHQ-8[8])	Acceptability measures
Education	Anxiety (GAD-7[9])	Pain (Doloplus-2[6])
Relationship to patient	Software issues	Burden (ZBI-short version[7])
Hours providing care to patient	Hardware issues	Software issues
Occupation		Hardware issues
Income		Caregiving Preparedness[3]

Marital Status		Caregiving Competence[4]
Patient residence		SF-12 Health Survey[2]
Paid caregivers for patient		Family Satisfaction with Advanced Cancer Care[10]
Number of caregivers for patient		
Caregiving responsibilities		
Feeling of choice in taking on caregiving responsibilities		
Availability of another caregiver if the participant is not available		
ADL/IADL		
Positive Aspects of Caregiving[1]		
Formal Care and Services questions		
SF-12 Health Survey[2]		
Caregiving Preparedness[3]		
Caregiving Competence[4]		

[1]Positive aspect of caregiving[20] [5]Neuropsychiatric Inventory [8]Patient Health Questionnaire-8[26]
[2]SF-12 Health Survey[21] [6]Doloplus-2[24] [9]General Anxiety Disorder-7[27]
[3]Caregiving preparedness[22] [7]Zarit Burden Interview–short version[25] [10]Family Satisfaction with Advanced Cancer Care[28]
[4]Caregiving competence[23]

3.2 Interviews, Focus Groups, Surveys, and/or Observations

A. Administration

For Aim 1 of the study, participants will be interviewed for up to 60 minutes to provide feedback on the I-HoME intervention. The same participants will be contacted within 2 months to provide additional feedback on the adapted version intervention; a follow-up questionnaire has been submitted to the IRB.

For Aim 2 of the study, questions will be administered to participants (family caregivers) at the first visit and within a week of completion of each televisit. Data from the subject's medical record will be obtained that are relevant to the study objectives (Table 2).

B. Study Instruments

For Aim 1, demographic measures will be collected from participants. A semi-structured interview guide will be used to conduct interviews, with open-ended questions.

For Aim 2, baseline demographic measures will be collected from the family caregiver and from the patient's medical record (see Table 1). Caregivers will be administered baseline, in-study, and post-intervention measures as outlined in Table 2.

4. Study Design

4.1 Study Population – All Aims

Caregiver Participants: Family caregivers of ADRD patients who meet the following criteria: age ≥ 65 years old and < 105 years old with advanced ADRD (more details below)

Provider Participants: Healthcare providers from Weill Cornell Medicine or Hospice medical directors

4.2 Inclusion Criteria

Aim 1

Healthcare provider criteria

- age 18 years or older
- a practicing medical provider (i.e., physician, nurse practitioner, physician assistant)
- experience working with caregivers of patients with ADRD
- English speaking.

ADRD LAR criteria
- age ≥ 18 years old and < 100 years
- English speaking
- Providing care to an ADRD patient who is age ≥ 65 years old and < 105 years

Aim 2
ADRD family caregiver criteria
- age ≥ 18 years old and < 100 years
- English speaking
- Providing care to an ADRD patient who is age ≥ 65 years old and < 105 years that is a stage 7a-f on the FAST scale
- Has access to an electronic device with cellular data or Internet connection

4.3 Exclusion Criteria – All Aims

Healthcare provider criteria
- Non-English speaking
- <18 years old

ADRD LAR/family caregiver criteria
- Non-English speaking
- <18 years old or >100 years old
- Does not provide care to an ADRD patient who is age ≥ 65 years old and < 105 years that is a stage 7a-f on the FAST scale
- Does not have access to an electronic device with cellular data or Internet connection

4.4 Strategies for Recruitment and Retention

Participants will consist of healthcare providers and caregivers of patients with a history of advanced ADRD. Recruitment of participants will be conducted at Weill Cornell Medicine's Center on Aging (Aim 1 and Aim 2) and the hospice medical director website (Aim 1 only).

Patient referral will be obtained from providers of the practice. Providers will present an Agree to Contact Sheet (included with our IRB submission) when appropriate. Potential participants will be sent a recruitment letter by a member of the research team to inquire about participating. We will follow up with family caregivers of the patients to whom we've sent a recruitment letter, via phone call or e-mail, one week following the mailing.

We will not target sample size by gender, race or ethnicity but hope to have a diverse pool of participants. We hope to recruit a total of 90 participants and estimate that we will screen 300 potential participants. A partial HIPAA waiver for recruitment purposes is requested in the IRB application. After a potential caregiver participant has been identified (for Aim 2) via our recruitment methods, study staff will review

charts and a study team physician will approve that a potential participant is medically eligible before consent and screening occurs.

Participants in Aim 1 will be compensated with a $75 gift card for their participation. Participants in Aim 2 will be compensated with a $25 gift card after completion of surveys during the duration of the study.

5. Registration Procedures

5.1 Subject Registration (WCM only)

Subjects will be registered within the WRG-CT as per the standard operating procedure for Subject Registration.

6. Study Procedures

6.1 Schedule of Assessments

Table 3. Schedule of trial events

AIM 1	Pre- Study	Time point 1	Time point 2
Screening (providers and LARs)	X		
Informed Consent		X	
Demographic Questions and interview		X	
Follow up interview for feedback on adapted version of I-HoME			X

Table 4. Schedule of trial events

AIM 2	Pre-Study	Day 1 (Study Visit)	Post visit #1	Post visit #2	Post visit #3	Post visit #4	Post visit #5	Post visit #6
Screening (Patient)	X							
Screening (Family caregiver)	X							
Informed Consent		X						
Demographic Questions		X						
Family caregiver survey data collection		X	X	X	X	X	X	X

7. Data Reporting / Regulatory Considerations

7.1 Data Collection

The data collection plan for this study is to utilize REDCap to capture data (Demographic, medical and survey data) for all enrolled subjects.

7.1.1 REDCap

REDCap (Research Electronic Data Capture) is a free data management software system that is fully supported by the Weill-Cornell Medical Center CTSC. It is a tool for the creation of customized, secure data management systems that include Web-based data-entry forms, reporting tools, and a full array of security features including user and group-based privileges, authentication using institution LDAP system, with a full audit trail of data manipulation and export procedures. REDCap is maintained on CTSC-owned servers that are backed up nightly and support encrypted (SSL-based) connections. Nationally, the software is developed, enhanced, and supported through a multi-institutional consortium led by the Vanderbilt University CTSA.

7.2 Regulatory Considerations

7.2.1 Institutional Review Board/Ethics Committee Approval

As required by local regulations, the Investigator will ensure all legal aspects are covered, and approval of the appropriate regulatory bodies obtained before study initiation.

Before initiation of the study at each study center, the protocol, the ICF, other written material given to the patients, and any other relevant study documentation will be submitted to the appropriate Ethics Committee. Written approval of the study and all relevant study information must be obtained before the study center can be initiated or the IP is released to the Investigator. Any necessary extensions or renewals of IEC/IRB approval must be obtained for changes to the study, such as amendments to the protocol, the ICF, or other study documentation. The written approval of the IEC/IRB together with the approved ICF must be filed in the study files.

The Investigator will report promptly to the IEC/IRB any new information that may adversely affect the safety of the subjects or the conduct of the study. The Investigator will submit written summaries of the study status to the IEC/IRB as required. On completion of the study, the IEC/IRB will be notified that the study has ended.

All agreed protocol amendments will be clearly recorded on a protocol amendment form and will be signed and dated by the original protocol approving signatories. All protocol amendments will be submitted to the relevant institutional IEC/IRB for approval before implementation, as required by local regulations. The only exception will be when the amendment is necessary to eliminate an immediate hazard to the trial participants. In this case, the necessary action will be taken first, with the relevant protocol amendment following shortly thereafter.

Once protocol amendments or consent form modifications are implemented at the lead site, Weill Cornell Medicine, updated documents will be provided to participating sites. Weill Cornell Medicine must approve all consent form changes prior to local IRB submission.

Relevant study documentation will be submitted to the regulatory authorities of the participating countries, according to local/national requirements, for review and approval before the beginning of the study. On completion of the study, the regulatory authorities will be notified that the study has ended.

7.2.2 Ethical Conduct of the Study

The Investigators and all parties involved should conduct this study in adherence to the ethical principles based on the Declaration of Helsinki, GCP, ICH guidelines and the applicable national and local laws and regulatory requirements.

This study will be conducted under a protocol reviewed and approved by the applicable ethics committees and investigations will be undertaken by scientifically and medically qualified persons, where the benefits of the study are in proportion to the risks.

7.2.3 Informed Consent

The investigator or qualified designee must obtain documented consent according to ICH-GCP and local regulations, as applicable, from each potential subject or each subject's legally authorized representative prior to participating in the research study. Subjects who agree to participate will complete an informed consent process and will be provided a copy of the finalized document.

Informed Consent for participants will occur just prior to their screener by in person or remote, oral consent methods. A member of the study team will review the ICF document, in-full, with each participant in person or by phone or videoconference, emphasizing the key information, allowing for questions, and reminding the potential subject that participation is entirely voluntary. In person and oral confirmation of consent will be documented by the study team member.

The initial ICF, any subsequent revised written ICF and any written information provided to the subject must approved by IRB prior to use. The ICF will adhere to IRB/IEC requirements, applicable laws and regulations.

7.2.4 Compliance with Trial Registration and Results Posting Requirements

Under the terms of the Food and Drug Administration Modernization Act (FDAMA) and the Food and Drug Administration Amendments Act (FDAAA), the Sponsor-Investigator of the trial is solely responsible for determining whether the trial and its results are subject to the requirements for submission to **http://www.clinicaltrials.gov**. Information posted will allow subjects to identify potentially appropriate trials for their disease conditions and pursue participation by calling a central contact number for further information on appropriate trial locations and trial site contact information.

7.2.5 Record Retention

Essential documents are those documents that individually and collectively permit evaluation of the study and quality of the data produced. After completion of the study, all documents and data relating to the study will be kept in an orderly manner by the Investigator in a secure study file. Essential documents should be retained for 2 years after the final marketing approval in an ICH region or for at least 2 years since the discontinuation of clinical development of the IP. In addition, all subject medical records and other source documentation will be kept for the maximum time permitted by the hospital, institution, or medical practice.

8. Statistical Considerations

Aim 1

Audio recordings from interviews will be transcribed verbatim. Content analysis[29], a method for classifying verbal and behavioral data into categories of similar meaning, will be used to analyze data. A deductive approach will be implemented. During open coding, short sections of text representing discrete concepts will be identified from transcripts and tagged with a code. This will be followed by focused coding, which involves comparing codes within and across interviews. Lastly, axial coding, where codes are compared between transcripts to develop a set of categories and/or themes, will be the third step of the coding process. A code book will be developed to systematize data analysis and ensure findings are reproducible. Interrater reliability and trustworthiness will be evaluated as part of the qualitative analytic process.[30] Two individuals with varied

backgrounds will independently review and code the transcripts. Discrepancies will be resolved through discussion until consensus is reached.

Aim 2

Feasibility will be assessed by examining accrual rates, attrition rates, adherence to the study protocol, hardware issues, software issues, and use of the intervention (e.g., frequency and duration of visits). Within study measures will be collected after every video visit to examine feasibility and acceptability of the intervention. Furthermore, an acceptability questionnaire will be administered at the end of the study to caregivers to obtain feedback on the intervention as a whole.

Quantitative care outcomes being collected fall into three main categories: patient outcomes (e.g., symptom-related measures), caregiver outcomes (e.g., burden, depression, anxiety, satisfaction, preparedness, competence, caregiver health), and healthcare utilization outcomes (e.g., number of visits, hospitalizations). Given the scope of this proposal, the number of caregiver participants (n=30) proposed for this study is aimed at establishing feasibility and acceptability and not efficacy. However, we will conduct preliminary efficacy analysis on outcomes at baseline and post intervention. Looking at pain (Doloplus-2 scale) as one of the secondary outcomes, with the assumption of a 40% improvement in scores based on a mean of 8.3 and SD of 6.5[31], there will be 80% power to detect an effect size of d=0.5, which is considered a moderate effect.

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