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

NCT04243538

Protocol approved on 9/5/2024

Research protocol – a protocol is not a proposal but rather a description of the involvement of study subjects or study subject data, and how the study will be carried out; *as applicable*, the protocol should include:

- **Protocol Content** *(not all content areas will be applicable to every protocol):*
  - Purpose and **Specific Aims** of the study

The Specific Aims of the study are: *(1) To employ an iterative user-centered design process to develop I-HoME for home hospice patients and their caregivers (CGs), (2) To conduct a single armed (N=10 CGs) pilot study with a focus on optimizing data collection protocols and the intervention before transitioning to, (3) To conduct a randomized pilot study evaluating the feasibility and potential efficacy of I-HoME (N=50 CGs) compared to usual care (N=50 CGs) and gather feedback on participants' experiences, and (4) To conduct a singled armed (N=6) pilot study delivering a modified version of the I-HoME intervention to assess feasibility.*

Study design, research methods, proposed intervention(s), rationale, hypotheses to be tested or issues to be addressed

This proposal seeks to develop and pilot test a multi-component technology-based care intervention, i.e., **I**mproving **Ho**me hospice **M**anagement of **E**nd of life issues through technology (I-HoME), that focuses on assessing and addressing patient symptoms and caregiver (CG) burden in the home hospice setting. I-HoME will consist of two components: (1) synchronous live video interactions between CGs and a hospice nurse; and (2) educational videos. In Aim 1, I will develop the I-HoME protocol by incorporating best care practices and evidence-based management of patient symptoms and CG burden. Employing a user-centered design approach that incorporates family CGs and providers, the intervention will be refined and adapted for home hospice care. In Aim 2, I will conduct a single armed pilot study which will implement the intervention over 6 weeks and collect data to further optimize and refine the study and intervention protocols. Lastly, in Aim 3, I will evaluate the feasibility and potential efficacy of I-HoME in the home hospice setting, by comparing it to usual care.

Aim 1: I-HoME Protocol and Intervention Development

Synchronous Live Video – Patient Symptoms. The patient symptom component of I-HoME will consist of weekly standardized assessment and management of signs/symptoms (e.g., pain, dyspnea, nausea, vomiting, agitation) experienced by the home hospice patient. In addition, visits on an as-needed basis (based on participant feedback and budget) can be requested by the patient, CG, and/or nurse interventionist, which may focus on a particular symptom or need. Development of the I-HoME protocol will focus on effectively evaluating and treating these symptoms along with other EoL symptoms through standardized assessments and management that incorporate education, non-pharmacologic and pharmacological therapies, and optimal use of hospice resources (e.g., respite, inpatient hospice care, etc.). A prototype intervention and manual of operations will be developed to incorporate existing best care practices and evidence-based research. Doxy.me is a platform that will be used to conduct synchronous live video interactions between hospice nurses and patients/caregivers. Doxy.me is a secure and HIPAA compliant service. A business associate agreement will be obtained with Doxy.me prior to starting the study.

Synchronous Live Video – CG Burden. The CG component of I-HoME will focus on a weekly, standardized assessment and management of burden experienced by the CG. In addition, visits on an as-needed basis (based on participant feedback and budget) can be requested by the CG and/or nurse interventionist, which may address a particular type of burden. Development of the I-HoME protocol will focus on effectively evaluating CG burden and addressing it through education, skill building, coping strategy development, and optimal use of hospice resources (e.g., social work/spiritual care visit, respite, inpatient hospice care, etc.). A prototype intervention and manual of operations will be developed to incorporate existing best care practices and evidence-based research. Doxy.me is a platform that will be used to conduct synchronous live video interactions between hospice nurses and patients/caregivers. Doxy.me is a secure and HIPAA compliant service. A business associate agreement will be obtained with Doxy.me prior to starting the project/ intervention.

Educational Videos. We will develop and use existing educational videos on patient symptoms and CG burden that reinforce the core principles delivered as part of the synchronous live video intervention. Videos will be developed and focus on topics around (but not limited to): *1) assessing symptoms, 2) understanding medications in the emergency medicine kit, 3) what to do when symptoms escalate, 4) the importance of recognizing and addressing CG burden,* and *5) an overview of hospice resources for family CGs*. Content for the videos will be based on existing best care practices and evidence-based research (literature review). We will receive feedback on the videos from patients, CGs, and hospice providers through our user-centered design protocol (see below). The revised educational videos will be shared based on the discretion of the hospice nurse interventionalist during the intervention phase (Aims 2 and 3). Additional video topics may be developed depending on the needs of the hospice providers and/or patients/CGs.

User-centered Design. After the initial prototype development of I-HoME, an iterative user-centered design process will be employed to refine the intervention. Feedback and performance data from individuals who will interact with a prototype of the intervention will be gathered. Ten home hospice providers (e.g., nurses, nurse practitioners, physicians) along with ten home hospice patients and ten family CGs will be interviewed individually and recruited from the Visiting Nurse Service of New York (VNSNY). Participants will be

compensated with a $50 gift card. Data collected during this process is outlined in **Appendix A**. Further details regarding recruitment, participant inclusion/exclusion criteria and informed consent forms are detailed in other sections of this protocol.

Aim 2: I-HoME single armed pilot study

The aim of the single armed pilot study will be to optimize the proposed intervention and the data collection protocols while addressing any challenges that arise during initial implementation of the project. I will recruit 10 CGs (10% of the proposed recruitment planned for the pilot RCT in Aim 3) and implement the I-HoME intervention for up to a 6-week period (the period of intervention for each CG will be dependent upon the patient's length of stay on home hospice). Based on the data gathered from the single armed pilot study (see **Appendix B** and **Table 1** for data collection materials), I will modify the data collection protocols and intervention prior to moving on and conducting the pilot RCT.

Intervention. CGs will have access to video visits with a research nurse interventionist on a scheduled (weekly) basis. The study team will either make an in-home visit or conduct a phone call with the CG (based on CG preference) at the start of the study to obtain consent and train the CG on the I-HoME intervention. Participants who we obtain written consent from will be seen in-person and provided with a tablet equipped with cellular data connectivity. Participants who we obtain oral consent from will be mailed a tablet equipped with cellular data connectivity. Participants will also be given a laminated user guide/help card and have access to technical assistance if hardware or software concerns arise or if an adverse event occurs. Software by Doxy.me will be used to conduct HIPAA compliant synchronous video visits. Phone visits will be conducted if video visits are unable to be done due to hardware or software issues.

Measurements. All participants will be assessed on the measures listed in Table 1 (see **Appendix B** for more details). Measures will be administered at baseline and in weeks 1, 2, 3, 4, 5 and 6. Baseline measures will be collected during the in-home/virtual visit by the research team and subsequent measures will be collected via phone call. Post-visit measures will be collected during each interview, and additional measurements will be collected during the final interview. Participants will be compensated $50 for an initial visit followed by $25 (by ClinCard) each time they complete a within study, and post-intervention survey phone call/electronic survey. Data collected in Aim 2 will allow identification of study design issues that may not arise in Aim 1 and will provide opportunity to make refinements to the intervention before proceeding with the full pilot RTC study (Aim 3).

Table 1.

Baseline measures		**Post-visit measures**
Patient (from medical chart)	**Caregiver**	**Caregiver**
Age	Age	Burden
Gender	Gender	Depression
Race/ethnicity	Race/ethnicity	Anxiety
Religion	Religion	Software issues
Education	Education	Hardware issues
Comorbidities	Relationship to patient	Patient symptoms if patient cannot answer
Hospice diagnosis	Hours providing care to patient	CaSES
DNI/DNR status	Number of CGs caring for the patient	**Caregiver (Final Interview)**
Medications	Occupation	CG Satisfaction
Income	Income	Feasibility questionnaire

Aim 3: I-HoME pilot RCT

For Aim 3, 100 CGs will be recruited from VNS Health hospice teams. The intervention will be randomized by nurse. Therefore, CGs of certain nurses will receive the I-HoME intervention (n=50) for up to six weeks while others will be recruited to receive standard home hospice care (n=50). Feasibility and potential efficacy measures will be administered at baseline and after each visit/weekly (timeline may change based on results obtained from Aim 2). Baseline measures will be collected during the in-home visit or via phone call by the research team and subsequent measures will be collected via phone call or electronic survey.

Intervention. CGs randomized to the intervention group will have access to live synchronous video visits with a research nurse interventionist on a scheduled (weekly) and as-needed basis (hours will be dependent on funding). The study team will either make an in-home visit or conduct a phone call with the CG (based on CG preference) at the start of the study to obtain consent and train the CG on the I-HoME intervention. This group will be educated about I-HoME and learn how to use the tablet to access videos and communicate with the interventionist. Participants will also be given a laminated user guide/help card and have access to technical assistance if hardware or software concerns arise or if an adverse event occurs. Software by Doxy.me will be used to conduct HIPAA compliant synchronous video visits. Participants in this study will continue to receive standard home hospice care in addition to the I-HoME intervention. Phone visits will be conducted if video visits are unable to be done due to hardware or software issues.

Standard Care Control. Participants in the standard care control group will receive home hospice services as usual. They will also receive a tablet with hospice resources. These participants will complete the same measures as participants in the intervention condition on the same timeline using identical assessment procedures.

Measurements. All participants will be assessed on the measures listed in Table 2 (see **Appendix B** for more details). Measures will be administered at baseline and in weeks 1, 2, 3, 4, 5 and 6. Validated surveys will be administered via phone by a research assistant. Post-visit measures for caregivers will be collected during each interview, and additional measures will be collected during the final interview. Participants will be compensated $50 for an initial baseline survey followed by $25 (by ClinCard) each time they complete a within study phone call/electronic survey. Post-intervention measures for patients will be collected from their medical chart in both groups. For the intervention group, the collection will start from study enrollment to 4 weeks after the final I-HoME intervention visit or the date of program end (which ever one is earlier). For the control group, the collection will start from study enrollment to 11 weeks after enrollment.

Table 2.

Baseline measures		**Post-intervention measures**	
Patient (from medical chart)	**Caregiver**	**Caregiver**	**Patient**
Age	Age	Burden	Hospice discharge reason
Gender	Gender	Depression	Use of non-home hospice services (inpatient care, respite care)
Race/ethnicity	Race/ethnicity	Anxiety	Number of nursing visits
DNI/DNR status	Religion	Software issues	Number of social work visits
Medications	Education	Hardware issues	Number of chaplain visits
Comorbidities	Relationship to patient	Patient symptoms	
Hospice diagnosis	Hours providing care to patient	CaSES	
	Number of CGs caring for the patient	**Caregiver (Final Interview)**	
	Occupation	CG Satisfaction	
	Income	Feasibility questionnaire	

Addition of patient participants for Aim 3

We will pilot patient participants (n=20) to answer a survey about their symptoms at baseline, 2 weeks, 4 weeks, and 6-weeks. The survey is the Edmonton Symptoms Assessment Scale (ESAS) which takes approximately 5 minutes to complete. We will also clarify to the patients that the ESAS data collected will not be shared with the clinical team and is for research purposes only. Enrollment of patients will help us understand the feasibility of interviewing hospice patients, and we will also analyze the differences in the ESAS scores from the dyad of caregiver and patient. Participants will be compensated a total of $50 for their participation. The gift card will be mailed after they have given oral consent and completed the baseline survey questions over the phone. We are suggesting an alteration of written consent and the use of oral consent. The patients are in hospice care and will likely find in-person visits or other forms of written or electronic consents to be burdensome. Their participation involves no more than minimal risks to the subjects, and the oral consent

obtained over the phone will not adversely affect the rights and welfare of subjects. Whenever appropriate, subjects will be provided with additional pertinent information after participation.

Addition of exit interviews for Aim 3

We will ask caregivers who participated in the Aim 3 randomized pilot study, nurses of these caregivers' care recipients, and the nurse practitioner interventionalists who conducted the telehealth visits to complete a recorded phone interview asking about their experiences with the I-HoME program. The interview will take approximately 30-45 minutes for the caregivers, 10-15 minutes for the nurses, and 30 minutes for the interventionalists. The interviews will be transcribed and anonymized to destroy any identifying information upon transcription. The questions asked are listed in Interview – Aim 3 documents below. The in-depth qualitative interviews will help us understand the feasibility and acceptability of the I-HoME intervention and ways to modify the intervention to make it more helpful for caregivers. Participants will be compensated $50 for their participation. The gift card will be mailed after they have given oral consent and completed the phone interview. The oral consent obtained over the phone will be less burdensome than other forms of written or electronic consents. The participation involves no more than minimal risks to the subjects, and the oral consent obtained over the phone will not adversely affect the rights and welfare of subjects.

Aim 4: Modified I-HoME single armed pilot study

The aim of the single-armed pilot study will be to examine the feasibility of providing I-HoME over the course of 3-weeks. This would include 2 tele-visits per week for up to 3 weeks instead of Aim's 3 weekly televisit over the course of 6 weeks. Our rationale for pilot testing this is to address the attrition concerns encountered in the existing data collected. While we found administering the tele-visits feasible, we also noticed that many caregivers didn't complete the six-week intervention (this was mainly because their loved one passed away earlier, so they didn't get the full benefit of the 6 visits). In Aim 4, we will pilot test a 3-week program, delivering 6 televisits, and examine its feasibility.

Intervention. A nurse practitioner interventionist will deliver the I-HoME intervention through a televisit twice a week for up to 3 weeks. The study team will conduct a phone call with the CG at the start of the study to obtain verbal consent and train the CG on accessing the televisit platform. Participants will also be mailed a user guide and have access to technical assistance if software concerns arise or if an adverse event occurs. Software by Doxy.me will be used to conduct HIPAA compliant synchronous video visits. Phone visits will be conducted if video visits are unable to be done due to hardware or software issues.

Measurements. All participants will be assessed on the measures listed in Table 3. Baseline CG demographic data will be collected during after consent and an exit interview will be conducted by phone when the participant completions the study. Participants will be compensated $50 for the initial survey, and $50 for the exit interview.

Table 3. Study measures for Aim 4

Caregiver
Age
Gender
Race/ethnicity
Religion
Education
Relationship to patient
Hours providing care to patient
Number of CGs caring for the patient
Occupation
Income

Sample selection/ Data sources. Describe characteristics of the subject population, such as their anticipated number, age, sex, ethnic background, and state of health. Identify criteria for inclusion or exclusion. If excluding certain racial or ethnic groups, please explain rationale and how exclusion may limit generalizability of findings. Explain the rationale for use of special classes of vulnerable subjects, such as pregnant women, children, mentally impaired, especially those whose ability to give voluntary informed consent may be in question. If vulnerable populations are to be used, investigators must deal thoroughly with the potential risk. If you need access to HIPAA-defined protected health information *(PHI-see attached list)* in order to screen for potential participation, for secondary data analysis or for other purposes and you do not plan to get authorization for access to this data from each individual you must request a *waiver of authorization* (see instructions below).

Aim 1: Home hospice providers (N=10) and family CGs (N=10) must be English speaking, 18 years of age or older, not blind, and either providing or receiving home hospice care. Home hospice patients (N=10) must be English speaking, 65 years of age or older, not blind, and enrolled in home hospice care. Patients with a terminal diagnosis of dementia or patients who have cognitive impairment and unable to sign a written/electronic informed consent will be excluded. A member of the research team will conduct this evaluation of the prototype at the patient's and/or CG's residence or through video conference. For home hospice provider participants, the user centered design visit will be conducted at VNSNY headquarters or through videoconference. All participants will be required to sign a written informed consent/electronic consent.

Each participant will be trained on the use of the prototype I-HoME care intervention. Specifically, participants will be asked about content, usability, feasibility/implementation concerns, anticipated challenges/benefits, and design features (**Appendix A**) after being shown the prototype. The aim of this process is to discover issues that users may have with the intervention. Information gathered as part of this process will be used to refine the intervention, which will include a manual of operations and educational videos before pilot testing begins. Study participation is expected to last 1-2 hours and subjects will be compensated with a gift card for their time.

Recruitment of subjects for this Aim is detailed further in this protocol. Participants recruited in Aim 1 will not be able to participate in Aim 2 or 3 of the study.

Aim 2: Home hospice CGs (N=10) must be English speaking, 18 years of age or older, not blind, and caring for a family member 65 years of age or older who is receiving home hospice care. Family CGs will also need to be providing 10 hours of hands on caregiving to the patient. The target population for this study are CGs of terminally ill patients. While CGs don't need any prior experience on how to use a tablet or understand the technology being implemented, if the participant doesn't have the ability to use the technology after an initial session with one of the research team members, the CG will be excluded from the study.

Recruitment of subjects for this Aim is detailed further in this protocol. Participants recruited in Aim 2 will not be able to participate in Aim 3 of the study.

Aim 3: Home hospice CGs (N=100) must be English speaking, 18 years of age or older, not blind, and caring for a family member 50 years of age or older who is receiving home hospice care. Family CGs will also need to be providing caregiving (e.g., hands on care, care coordination) to the patient on a weekly basis. The target population for this study are CGs of terminally ill patients. While CGs don't need any prior experience on how to use a tablet or understand the technology being implemented, if the participant doesn't have the ability to use the technology after an initial session with one of the research team members, the CG will be excluded from the study.

Recruitment of subjects for this Aim is detailed further in this protocol. Participants recruited in Aim 3 will not be participants in Aim 1 or 2 of the study.

Hospice patients (n=20) will be referred by caregivers that are enrolled in the study. The study team will ask the caregiver if the patient would be open to participating. Patients with a hospice diagnosis of dementia will not be considered.

For the exit interviews, CGs must have completed at least one telehealth visit within the I-HoME randomized pilot study (Aim 3 intervention arm), be English speaking, and 18 years of age or older. Nurses must have had their patient's family CG receive at least one telehealth visit in Aim 3 intervention arm, be English speaking, and 18 years of age or older. Nurse practitioner interventionalists must have delivered telehealth visits for the I-HoME study, must be English speaking, and 18 years of age and older.

Aim 4: Home hospice CGs (N=6) must be English speaking, 18 years of age or older, and not blind, and caring for a family member 18 years of age or older who is receiving home hospice care. Family CGs will also need to be providing caregiving (e.g., hands on care, care coordination) to the patient on a weekly basis. The target population for this study are CGs of terminally ill patients. While CGs don't need any prior experience in understanding the technology (televisits) being implemented, if the participant doesn't have the ability to use the technology after an initial session with one of the research team members, the CG will be excluded from the study. Participants recruited in Aim 4 will not be participants in Aim 1, 2, or 3 of the study.

Procedures for recruiting study subjects. Describe how potential study subjects will be approached. The protocol needs to include any telephone scripts or letters to be used for recruitment purposes, and incentives used to solicit participation.

Aim 1: VNS home hospice providers will be recruited via email provided by VNSNY hospice collaborators (see email recruitment template). Hospice providers who respond to the email with interest in participating will be scheduled for an in-person meeting at VNSNY headquarters or via video conference (e.g., Zoom – HIPAA compliant, Doxy.me) to describe the study and obtain written/electronic informed consent. Electronic informed consent will be obtained through Doxy.me or Docusign which are both HIPAA compliant and have electronic signature capabilities) Interviews will either be done individually or in focus groups. Signed electronic consents will be stored on a secure Weill Cornell server. Zoom and Doxy.me provides a secure HIPAA compliant platform to conduct synchronous video meetings.

One hospice team will work with a VNSNY-supervised research assistant (RA) and the PI to identify potential patient/CG participants that meet criteria (based on inclusion/exclusion criteria) for Aim 1. Weill Cornell and VNSNY are co-engaging one or more RAs – they will be hired by Weill Cornell but will also be brought on as an intern or volunteer at VNSNY. The RA(s) will go through VNSNY orientation processes and HIPAA training. In their VNSNY site role, the RA or the PI will contact subjects to briefly describe the project by phone (see telephone script A) or via video conference (e.g., Zoom, Doxy.me). The PI's role in recruiting patients and caregivers will happen after a VNSNY staff person or the RA co-hire receives permission from the patient to release their name and contact information for the study. Patient and CGs interested in participating will be scheduled for an in-home visit or via video conference (e.g., Zoom, Doxy.me) to describe the study and obtain written/electronic informed consent. Electronic informed consent will be obtained through Doxy.me or Docusign which are both HIPAA compliant and have electronic signature capabilities. The RA or PI will transmit participant data to Weill Cornell through the VNSNY approved secure web portal.

No external investigators (unless they are a VNSNY employee or VNSNY volunteer/intern) will be given names or contact information until subject approval is obtained through a VNSNY provider.

Aim 2: For the single armed pilot phase, I will be collaborating with home hospice teams (each team consists of 5-7 nurses taking care of patients in a certain region of NYC). Family CGs will be screened for study eligibility within 7 days of their home hospice admission through chart review. Screening will be conducted regularly by the research team. Prior to reaching out to potential participants, the research team will contact the nurse caring for the patient and CG to confirm that it would be appropriate to contact the CG for the study. Weill Cornell and VNS Health are co-engaging one or more research staff through a subaward – they will be hired by VNS Health and performing the initial screening/recruitment. VNS Health staff will contact subjects by phone to inquire about their interest in participating (see telephone script B). The RA will be educated about the I-HoME intervention and answer questions that subjects may have during the phone call. If there is interest expressed by a CG over the phone, a research team member will reach out to conduct an in-home visit or phone call to describe the study and obtain written or oral informed consent (based on CG preference). Participants will be provided a copy of the informed consent after consent is obtained (in-person or it will be mailed to them).

We will also be implementing a flyer to help recruit participants for the study. The flyer will be provided to hospice nurses to distribute to CGs they feel would be appropriate for the study. The flyer will provide a number for CGs to call if they are interested in participating. CGs that meet the inclusion and exclusion criteria will be consented to participate in the study by the research team.

No external investigators (unless they are a VNS Health employee or VNS Health volunteer/intern) will be given names or contact information until subject approval is obtained through a VNS Health provider.

Aim 3: For the pilot RCT, I will be collaborating with VNS Health home hospice teams (each team consists of 5-7 nurses). These two teams will be randomized to receive the intervention (I-HoME) or standard care at the nursing level. Since this is a pilot study and the primary aim is to assess for intervention feasibility, we acknowledge that we will not be able to control for certain differences. We will work with VNS Health hospice leadership to select hospice teams that serve similar patient populations. In both hospice teams, family CGs will be screened for study eligibility within 7 days of their home hospice admission through chart review. Screening will be conducted regularly by the research team. Prior to reaching out to potential participants, the

research team will contact the nurse caring for the patient and CG to confirm that it would be appropriate to contact the CG for the study. Weill Cornell and VNS Health are co-engaging one or more research staff through a subaward – they will be hired by VNS Health and performing the initial screening/recruitment. VNS Health staff will contact subjects by phone to inquire about their interest in participating (see telephone script C and D). If there is interest expressed by the CG over the phone, a research team member will reach out to conduct an in-home visit to describe the study and obtain written informed consent.

No external investigators (unless they are a VNSNY employee or VNSNY volunteer/intern) will be given names or contact information until subject approval is obtained through a VNSNY provider.

Hospice patients (n=20) will be referred by caregivers that are enrolled in the study. The study team will ask the caregiver (after they have been consented) if the patient would be open to participating in the study to provide ratings on their symptoms. Patients with a hospice diagnosis of dementia not be considered for the study. Eligible patients will be contacted by phone by a research team member.

For the exit interviews, family CGs who participated in the pilot RCT (Aim 3) will be screened for study eligibility. VNS Health staff will contact eligible CGs by phone to inquire about their interest in participating (see telephone script E). If there is interest expressed by the CG over the phone, a research team member will reach out to complete the verbal consent and recorded phone interview. Nurses and nurse practitioner interventionalists will be contacted via email to inquire about their interest in participating (see email template F and G). If there is interest expressed, a research team member will reach out to complete the verbal consent and recorded phone interview.

Aim 4: This study will involve collaboration with VNS Health home hospice teams. Family CGs will be screened for study eligibility within 7 days of their home hospice admission through chart review. Screening will be conducted regularly by the research team. Prior to reaching out to potential participants, the research team will contact the nurse caring for the patient and CG to confirm that it would be appropriate to contact the CG for the study. VNS Health staff will contact subjects by phone to inquire about their interest in participating (see telephone script H). The RA will be educated about the I-HoME intervention and answer questions that subjects may have during the phone call. If there is interest expressed by a CG over the phone, a research team member will describe the study, obtain verbal informed consent, administer demographic questions, and train CGs how to access the telehealth platform. Participants will be mailed a copy of the informed consent after consent is obtained. No external investigators (unless they are a VNSNY employee or VNSNY volunteer/intern) will be given names or contact information until subject approval is obtained through a VNS Health provider.

Consent forms and additional PHI authorizations. A person *consents to participate in research* and *authorizes use and disclosure of protected health information*. Consent forms should be clear, easy to understand, and written at a recommended fifth grade reading level. If children under 18 years of age will be included in the study, then parental consent may also be required. If consent forms are not deemed necessary, the rationale for this should be included in the statement of protection of human subjects in the proposal body. The investigator is responsible for retaining signed consents in the research files. Because a consent form documents an agreement between two parties, the subject should be given a copy to keep as well. *A list of elements required in an informed consent form is attached along with a prototype consent form.* If protected health information (PHI) will be recorded for patients consenting to research then additional elements need to be included in the consent or a separate authorization is required. Minimal requirements for an authorization form are on page 6 of this application packet.

Data to be employed, data collection procedures, data collection instruments, if applicable (okay to submit instruments in draft form).

Please see Table 2, Appendix A and Appendix B for data collection instruments at the end of the document. Data collection procedures will be conducted by trained research staff and done in-home, at VNSNY headquarters, by phone, by videoconference or online surveys as outlined in the protocol above.

Brief overview of **analytic methods**.

Feasibility will be assessed by examining accrual rates, attrition rates, adherence to the study protocol, hardware/software issues, and use of the intervention (e.g., frequency and duration of visits, number of educational video views). A feasibility questionnaire will be administered at the end of the intervention to CGs and to patients (if alive).

To measure potential efficacy, we will use mixed models (MMs) to analyze specific outcomes (i.e., symptoms, CG burden, hospitalization, etc.). MMs do not assume that each subject will contribute data at all-time points and so they can be used for data with complex attrition patterns. In these models, the subject's initial status (intercept) and the change in their status (slope) will be treated as random effects. The variables of group, time, the interaction of group and time, and any variable that differs between the two conditions at baseline or other variables of theoretical interest, expectation for inclusion in models from the literature, or near significance of difference by conditions will be modeled as fixed effects. Nurses will be examined in models as levels of a random classification factor. For all variables, four models will be tested: a linear effect of time, a log-linear effect of time allowing for more rapid change at the beginning of the study, a quadratic effect of time with no random slope for the quadratic term, and a quadratic effect of time with the slope of the quadratic term also being allowed to be random. Model selection will be done using the Bayesian Information Criterion[77], a measure of model misfit with a penalty added for extra parameters, with inferences only being made from the best fitting model. We will also test for a random intercept and random effect of time by hospice nurse to control potentially for nesting by nurse. Given the small number of hospice nurses we anticipate to be involved in the study, we do not expect either random effect to be statistically significant and plan to drop it from the model if it is not. We will also test for effects in CGs who are bereaved very early in the study.
Mixed model analysis will be conducted on seven outcomes.

For post-test power assessment, the selection of 100 patient–CG dyads is based on power calculations with an all-cause attrition rate on not filling out post-test assessments of 10%, leaving 90 dyads. For post-test comparisons of post-intervention measures under a two-tailed hypothesis, we will have 80% power to detect a group-by-time interaction with an effect size of d=0.66*,* which is regarded as a medium-large effect size. A data collection protocol whereby data are collected at baseline and in weeks 1, 2, 3, 4, 5, and 6 would correspond to 7 measurements for subjects who complete the 6-week intervention/pilot test. To conduct a power-analysis we conducted a simulation to model attrition directly. We assumed everyone would have at least 1 measurement after hospice discharge, including patients who died during week 1 of the intervention. The mortality rate modeled using samples drawn from data on 1,000 home hospice patients was 35% at four weeks, 62% at eight weeks, and 72% at twelve weeks. This means we would have 7 measurements on approximately 28% of the data.

Our power to detect effects will depend largely, on how quickly the intervention is successful. With two time points for each subject we will have 80% power to detect an effect size of d=0.57 on any outcome, which is considered a moderate effect. If it takes the full 7 time points for the full effect of the intervention to be realized our power will be reduced and we will require a large effect (d=0.8) to obtain 80% power. A 25% reduction in burden reported by family CGs corresponds to an effect size of 0.71. Under a two-tailed hypothesis test, if the intervention is successful by week 1, we would have 94% power to detect an effect of this size. We would have 70% power for a two-tailed hypothesis test across 7 time points.

Statement of the risks/benefits for the study subjects.
How **privacy, confidentiality** and the rights of human subjects will be protected. In order to safeguard the privacy of study participants, protected identifiers (e.g., a person's name) normally should not be recorded on the same instrument where you record data obtained from study subjects. A justification must be made in the protocol as to why the research cannot be conducted in any other way if you believe you need both protected identifiers and information obtained from subjects on the same data collection form.

For Aim 1, study participants will be interacting with a research team member to test a prototype of the I-HoME intervention. Feedback about the prototype intervention (I-HoME) along with private identifiable information will be collected via questionnaires and audiotaped interviews from home hospice patients, CGs, and providers. Data will be collected individually, in-person or via video conference. Patients who opt for participation via videoconference (e.g., Zoom) will be able to sign an electronic consent through Weill Cornell's REDCap database (see example of a consent form using this link *https://redcap.ctsc.weill.cornell.edu/redcap_protocols/surveys/?s=RD7NHHK3P9*). While there is a small risk of breach of confidentiality, we will take steps to minimize the risk. Data obtained from participants' feedback of the I-HoME intervention will be stored on the REDCap database, a secure web-based application hosted by the Weill Cornell Clinical and Translational Science Center. Demographic and survey data collected at the subject's home will be entered into REDCap while on-site in order to eliminate the risk of stolen or lost data during transportation. Data from interviews that cannot be stored on REDCap will be tape recorded and transferred to the PI's password protected computer which is protected on Weill Cornell Medicine's secure server. For interviews being conducted at the subject's home, an encrypted audio recorder will be used to reduce risk of data being accessed if stolen.

For Aims 2 and 3, all study participants will be interacting with a research assistant while those in the intervention group will also be interacting with a nurse interventionist delivering the I-HoME intervention. Human subject involvement will include data collected from home hospice patients, CGs, and providers by a research assistant. Data will be gathered via: (1) initial baseline assessment done in-person, (2) questionnaires administered by telephone or online via a REDCap weblink during the course of 6 weeks, (3) post-intervention questionnaires administered by telephone or online via a REDCap weblink 4 weeks post-intervention and (4) the patient's medical record. The patient's medical records will be reviewed by the RA at the beginning of the study to collect demographic data and at the conclusion of the study to collect post-intervention data. Private identifiable information will be collected and data will be linked to living individuals. Only members of the research team will have access to the materials.

While there is a small risk of breach of confidentiality, we will take steps to minimize the risk for participants in Aims 2 and 3. The I-HoME software will be provided by Doxy.me, which provides a secure HIPAA compliant platform to conduct synchronous video visits. Data collected for Aim 2 and 3 will be stored on the REDCap database. Precautions will be taken to protect the security of the data collected and the privacy of the individuals from whom we collected the data. All protected identifiers will not be recorded on the same instrument where record data will be obtained from study subjects. Demographic and survey data collected at the subject's home will be entered into REDCap while on-site in order to eliminate the risk of stolen or lost data during transportation. For interviews being conducted at the subject's home, an encrypted audio recorder will be used to reduce risk of data being accessed if stolen.

There is a minimal risk of subject distress during the administration of surveys (see Appendix B) to patients and CGs during the pilot phase in Aims 2 and 3. As a result, I will have safeguards in place to address subject's distress. All study subjects will be free to refuse to answer any questions or to discontinue study participation at any time. In all cases where there might be concerns for suicidality, referrals to a hotline and mental health services will be provided. In addition, the PHQ-9 will be administered to the subject. If subjects do not answer "not at all" to question 9 in the PHQ-9 survey, the research team member will remain with the participant and call to a trained professional to speak with the participant to create a safety plan which may include a call to 911 if warranted.

For studies that require a DSMB, a **DSMB plan** should be provided in the protocol which should include: number of members, meetings (how often), data that will be reviewed during the meetings and plan regarding dissemination of summary reports (i.e. meeting minutes) to the IRB.

DATA AND SAFETY MONITORING PLAN

PI of Grant: Veerawat Phongtankuel, MD, MS

Grant Number: 1K76AG059997-01A1

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

Brief Description of Intervention: This proposal aims to develop and evaluate a multi-component technology-based care intervention, i.e., **I**mproving **Ho**me hospice **M**anagement of **E**nd of life issues through technology (I-HoME), that focuses on assessing and addressing patient symptoms and CG burden in the home hospice setting through synchronous live video visits and educational videos.

NIH Phase III Clinical Trial? No

Multiple Site Trial? No

Specific Aims:

Aim 1: *Employ an iterative user-centered design process to develop I-HoME, a multi-component technology-based care intervention, for home hospice patients and their CGs. Development of I-HoME will incorporate best care practices and evidence-based management along with feedback from key stakeholders, i.e., patients (N=10), CGs (N=10), and hospice providers (N=10), to inform and refine the intervention.*

Aim 2: *Conduct a single armed (N=10 dyads) pilot study with a focus on optimizing data collection protocols and the intervention.*

Aim 3: *Conduct a randomized pilot study to evaluate the feasibility and potential efficacy of I-HoME (N=50) compared to usual care (N=50). Feasibility will be assessed by examining overall accrual, attrition, adherence to the study protocol, and use of the intervention; efficacy will be assessed using patient (symptoms), CG (burden, depression, anxiety, satisfaction with care), and systems (hospice live discharges, hospitalizations) outcomes.*

Brief Description of Project Design

For Aim 1, ten home hospice providers (e.g., nurses, nurse practitioners, physicians) along with ten home hospice patients and their ten family CGs will be interviewed individually and recruited from the Visiting Nurse Service of New York (VNSNY) to provide feedback on the I-HoME intervention.

For Aim 2, ten patient/caregiver dyads will be recruited for the i-HoME intervention which will be delivered for up to a 6-week period. Based on the data gathered from the single armed pilot study, modifications will be made to the data collection protocols and intervention prior to moving on and conducting the pilot RCT.

For Aim 3, 100 patient and CG dyads will be recruited from VNSNY and randomly assigned, by hospice team, to either I-HoME (n=50) or to standard home hospice care (n=50) for twelve weeks. Feasibility and potential efficacy measures will be administered at baseline and in weeks 1, 2, 3, 4, 5 and 6. Post-intervention measures will be collected at the end of the intervention 4 weeks after a patient's death.

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A. PARTICIPANTS SAFETY

A.1 Adverse Event and Serious Adverse Event Collection and Reporting

I have identified two categories of adverse events: serious adverse events and safety alerts. Members of the research team will be trained to track these events through participant self-report and/or interactions with participants. Pre-intervention adverse events are issues that are identified and recorded by study personnel during interview discussions and are unrelated to the intervention. Adverse events are situations that occurred during the intervention period and are identified by members of the research team during any follow-up assessment or any off-protocol interaction with a participant. Adverse events occur anytime following randomization until study completion. Safety alerts will be identified during any interview or anytime following randomization until study completion.

Below are the specific events that trigger a formal response:

Serious Adverse Events
- Hospitalization of caregiver
- Institutionalization of caregiver
- Emergency room visit of caregiver
- Death of caregiver

Safety Alerts
- Severe medical problem of caregiver
- Patient and/or caregiver abuse
- Patient and/or caregiver threatens to harm him or herself or others

A summary of all serious adverse events and safety alerts (i.e., those that are anticipated and related to the study) will be reported to the NIA Program Officer and Safety Officer quarterly, unless otherwise requested by a Safety Officer.

When serious adverse events occur that are unanticipated (i.e., events that are not listed above) and are related to the study (i.e., there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research), they will be reported to the NIA Program Officer within 48 hours of the study's knowledge. Unanticipated problems involving risks to study participants or others will also be reported to NIA within 48 hours. Unanticipated problems are defined as any incident, experience, or outcome that is unexpected given the research procedures that are described in the protocol-related documents; related or possibly related to participation in the research; or suggest that the research places participants at a greater risk of harm than was previously known or recognized.

Dr. Veerawat Phongtankuel, the PI, will be responsible for ensuring participants' safety on a daily basis. He will also evaluate the progress of the study, review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses.

A.2 Frequency of Data and Safety Monitoring

When an alert or adverse event is identified by a member of the research team, the event must be reported to Dr. Phongtankuel within 24 hours and recorded on the Alert/Adverse Event Form in the study's REDCap database. Dr. Phongtankuel will report any adverse events related to the study to the Weill Cornell Medicine IRB and the VNSNY IRB, according to IRB policy. When serious adverse events occur that are unanticipated (i.e., not listed in the Data and Safety Monitoring Plan) and that are related to the study, they will be reported to the NIA Program Officer within 48 hours of the study's knowledge of the serious adverse event.

A.3 Protection Against Study Risks

Informed Consent

Screening of potentially eligible participants (hospice patients and caregivers) will be conducted by telephone by a study staff member using an IRB-approved screening template. Study staff will explain the study as well as randomization procedures (if applicable), and answer any questions.

If the dyad (hospice patient and caregiver) agrees to participate after hearing the above description, a scheduled visit will be arrange. During this face to face visit, the hospice patient and caregiver participant will be asked to sign a written informed consent to be part of the study. A copy of the consent will be provided to them as well. Participants enrolled in the study will then undergo a baseline interview and proceed with the study protocol as outlined in the other sections of the grant. Throughout the study period and with each interaction with the study team, each participant will be encouraged to ask questions and told that even if they consent to be in the study, they are free to withdraw from it at any time, for any reason.

The main points that will be addressed by study staff obtaining informed consent include explaining why the current research study is being conducted, the source of funding for the project, and what purpose the proposed research serves. Additionally, the subject will be made aware of who is responsible for conducting the research as well as how participants, including themselves, are selected for participation in the research.

The study staff will explain in explicit detail what will be asked of the participants if they agree to participate in the study and estimate the potential time commitment involved. Participants will know what their responsibilities will entail, what risk or benefit may be involved and what potential costs could be incurred should they agree to participate. The study staff will underscore the importance placed upon maintaining participant confidentiality as well as their rights while involved in the study, which includes the right to withdraw participation at any time during the research due to the fact that their participation is entirely voluntary in nature.

The informed consent will also contain a section dedicated to explaining what constitutes protected health information and how this information remains confidential per HIPAA (Health Insurance Portability and Accountability Act) guidelines.

Finally, the informed consent will provide contact information for both Principal Investigators, the Office for the Protection of Research Subjects, and the Site PI contact. All informed consent processes will adhere to the policies set forth by the Institutional Review Board. All informed consent forms will be stored in a locked file cabinet or locked computer file in a locked office to maintain the privacy of all study participants.

In summary, the consent form will include a description of all study procedures, information regarding the risks and benefits of participation, contact information for study staff who can answer participants' questions, and alternatives to participation in the study. The consent form will also state that: (1) participation is voluntary, (2) participants can refuse to answer any questions, (3) participants can withdraw from the study at any time, (4) all responses will remain confidential, and (5) participation in the study is not related to care received while in hospice.

B. INTERIM ANALYSIS

No interim analysis is planned, due to the fact that this is a small pilot study of an intervention with minimal risk; and because this is a feasibility and not an efficacy trial.

C. DATA AND SAFETY MONITORING

C.1 Content of Data and Safety Monitoring Report

The content of the data and safety monitoring report will include: the overall study status, information on participant characteristics (e.g., age, gender, ethnicity), as well as information on actual vs. targeted recruitment, reasons for ineligibility, and summary information on adverse events and safety events.

C.2 DSMP Safety Monitor

The following individual has accepted the position of safety monitor as part of the DSMP. The proposed individual is independent of Weill Cornell Medicine and the Visiting Nurse Service of New York.
The selected member of the committee has expertise in aging/geriatrics, intervention implementations, statistical analysis techniques, research design and behavioral intervention research.

Developing and piloting a multi-component technology-based care intervention to address patient symptoms and caregiver burden in home hospice.
Proposed member of DSMP

Name	Title	Institution
Amy Kelley, MD	Associate Professor	Mount Sinai

C.3 Protection of Confidentiality

Data will be presented in a blinded manner during the open sessions with the safety monitor and in the reports. At the DSMP meetings and in the data reports, data and discussion are confidential. The safety monitor will not know the identities of study participants.

C.5 Safety Monitor Responsibilities

The responsibilities of the safety monitor include to:

1. Review and recommend approval or request modification to the IRB-approved research protocol and consent documents.
2. Review and recommend approval of the study's DSMP, Manual of Procedures, and safety monitor periodic report templates.
3. Periodically evaluate the progress of interventional study(s), including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome.
4. Make recommendations to NIA program staff concerning the continuation, modification, or conclusion of the trial.

C.6 DSMP Processes

The safety monitor will meet every 6 to 9 months, either in-person or by teleconference call to review study progress, data quality, and participants' safety. Additional meetings will be scheduled if deemed necessary by the safety monitor or the NIA PO. The first meeting will be held prior to the beginning of data collection in order to review study protocols and establish/approve the protocols for identifying, reviewing, and reporting adverse events and unanticipated problems. The safety monitor in collaboration with the PI established the schedule for data monitoring and reporting. The Chair or the NIA may call an emergency meeting with the safety monitor should participant safety questions or other unanticipated problems arise.

Meetings are closed to the public because discussions may address confidential participant data. The Principal Investigator (Phongtankuel) and members of his staff will attend the meetings. Meetings may be convened as conference calls as well as in-person.

C.7 Meeting Format

DSMP meetings will consist of open and closed sessions. Discussion held in all sessions is confidential. The Principal Investigator and key members of the study team attend the **open sessions.** Open session discussion will focus on the conduct and progress of the study, including participant accrual, protocol compliance, and problems encountered. Unblinded data are not presented in the open session.

The safety monitor will attend the **closed session**. The study statistician may be present, at the request of the safety monitor. Any data blinded by study group and, as necessary, unblended data, are presented during the closed session.

If necessary, an **executive session** will be attended by the safety monitor. The executive session will be held to identify and discuss the safety monitor's recommendations to the NIA. The study staff may be present, at the request of the safety monitor, during the executive session.

Each meeting must include a recommendation to continue or to terminate the study and whether the safety monitor has any concerns about participant safety. A recommendation to terminate the study may be made by the safety monitor and she should provide such a recommendation to the NIA immediately by telephone and email. After the NIA Director makes a decision about whether to accept or decline the safety monitor's recommendation to terminate the study, the PI is immediately informed about his decision.

Written agreement that researcher will adhere to the reporting requirements of the VNSNY IRB including agreement to submit a **study closure report within 60 days** of the end of primary data collection or within 60 days of completing primary objective analysis if study is using secondary data. The investigator also agrees to submit a summary of main project findings when available.

Dr. Veerawat Phongtankuel has agreed to adhere to the reporting requirements of the VNSNY IRB including agreement to submit a study closure report within 60 days of the end of primary data collection or within 60 days of completing primary objective analysis if study is using secondary data. He also agrees to submit a summary of main project findings when available.

Request for Waiver of Authorization for HIPAA compliance. Internal and external investigators requesting access to data or datasets that contain protected health information (PHI) without obtaining individual authorization must request a waiver of authorization. *Attached is the request form.* You should specify the participant identifiers and the protected health information needed and how your protocol addresses each of the waiver criteria that must be met in order for the IRB to approve the request.