COVER

TITLE: A Telenovela Intervention for Caregivers of African-American and Hispanic Hospice Patients

DATE: 3/4/2025.

CLINICAL TRIALS NUMBER: NCT06835764

Date: ___3/4/2025___
Principal Investigator: __ Dulce M. Cruz-Oliver ___
Application Number: __IRB00457633__

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JHM IRB EFORM E – EXEMPT PROTOCOL

- **Please use this form to describe a research protocol that may qualify for an exemption. Types of research that may meet the criteria for exempt review include: educational research, survey/interviews, benign behavioral interventions, and secondary research.**
- **PLEASE NOTE:** If the project is ONLY comprised of **secondary research** data analyses (retrospective or prospective medical record/biospecimen review, secondary analysis of approved study data), please do NOT use this form and instead use the eForm S for your research protocol template.
- **Please provide complete information for each item below. If an item is inapplicable to your research study, explain why.**
- **When submitting JHM IRB eForm E (new or revised), enter the date submitted, the name of the PI, and the eIRB application number in the header at the top of the form.**

TITLE: Enhancing Self-Efficacy and Lowering Anxiety Through a Telenovela Intervention for Caregivers of African-American and Hispanic Hospice Cancer Patients*: Pilot Trial*

1. Purpose/Aims:

This proposal aligns with the Sidney Kimmel Comprehensive Cancer Center (SKCCC) strategy to use innovation to reduce the cancer burden among minorities, using novel patient care approaches to improve the community's health, specifically within the SKCCC catchment area (MD/Baltimore). It also aligns with the mission of Johns Hopkins University (JHU) to achieve its diversity, equity, and inclusion aims. Hospice in Maryland cared for more than 20 thousand people in 2021, of whom 85% had a primary admission diagnosis of cancer, and 33% self-identified as part of a minority group.[1] The proposed project will continue the work with culturally tailored training for underrepresented hospice family caregivers (HFCGs). It will test HFCGs' improvement in self-efficacy for symptom management and lower their anxiety, thus reducing care recipients' emergency room visits and hospice disenrollment—two key markers of poor End-of-Life (EOL) care outcomes. The Aims include:

- ***Specific Aim 1:*** *Investigate the preliminary efficacy of delivering NOVELA to African American (AA) and Hispanic HFCGs of cancer patients.*
- ***Specific Aim 2:*** *Evaluate the benefits of NOVELA as perceived by hospice staff.*

2. Background: (briefly summarize literature including current practice or educational guidelines, current institutional practice or standard of care, and any other relevant information to justify the research)

Over 1.7 million Medicare beneficiaries received hospice services in 2021.[2] Most hospice care for cancer patients is delivered at home, typically engaging a family caregiver who is willing and able to care for the patient. HFCGs play a crucial role at EOL, providing, on average, 40 to 60 hours of care a week[3]. HFCGs save the healthcare system billions of dollars (e.g., hospitalization, nursing home placement). HFCGs work with hospice teams to implement patient care plans. They tend to the day-to-day needs of the patient, administer medications for comfort, and provide emotional and spiritual support. While many HFCGs find meaning in their role, they are also likely to suffer from depression, anxiety, stress, and poor physical health compared to non-HFCGs.[4, 5, 6] Supporting HFCGs is essential for their well-being and those receiving care. [6]

Dr. Cruz's prior research aimed to improve care for home hospice patients through telehealth visits and educational videos.[7,8,9, 10] Prior work, funded by the Beeson supplement and CRF 2022, included developing culturally tailored videos. The proposed project will expand the work with multiple methods randomized pilot test of NOVELA's preliminary efficacy in reducing caregiving anxiety (primary outcome) in underrepresented (Hispanic and African American) HFCGs of cancer patients. African Americans are the second-largest racial group receiving hospice care[2], and Hispanics are the second-largest ethnic group in the US.[11] Over 60% of the population of Baltimore is African American, and over 7% is Hispanic.[12] These demographic profiles make the proposed project scalable. Education is crucial to EOL caregiving. Dr. Cruz has researched information needs

among HFCGs and identified gaps in knowledge.[8] Knowledge gaps regarding symptoms can lead to unprepared HFCGs and poor outcomes.[13]

Video is increasingly utilized for patient and family education as it provides visual and relatable information that can capture complex medical and emotional scenarios.[14,15,16] Telenovelas, a form of television drama used widely in Latin American countries, are a creative approach to video education that uses storytelling to teach about health. Learners are more engaged when watching telenovelas, leading to rich discussions of the story and potentially initiating changes in attitudes and behaviors.[17] The use of telenovelas in hospice shows significant promise as a mode of education; it could enhance the ability of HFCGs to manage personal distress or pain for the care recipient.[18,19] Our preliminary work (R01CA203999) found subjects were 12% more likely to view telenovelas than video-recorded PowerPoint videos. Watching telenovelas produced better content recall and follow-up actions than watching a non-telenovela format video.[8] In a follow-up study, we developed an interventionist-led conversation guide as a companion for the telenovela.[7] The intervention, which includes the video series and the conversation guide, is named *NOVELA* (short for tele*novela*). Our preliminary single-arm trial found NOVELA feasible and acceptable in the hospice setting,[10] with promising improvements in caregiver anxiety symptoms.[20] Thus, storytelling and culturally tailored videos can be powerful tools to educate family caregivers of hospice patients.

Yet, there is a dearth of evidence-based educational resources for HFCGs. The literature shows a need for cultural tailoring, but many HFCGs are unlikely to have access to culturally appropriate resources.[21, 22,23, 24, 25] Culturally tailored education, such as telenovelas, effectively improves knowledge and behaviors[26-29]. Interventions to provide caregivers with knowledge and skills[30,31] posits that people who believe they can exercise control over challenges (self-efficacy for symptom management) are less likely to be anxious.[32] These factors are associated with improved HFCG outcomes.[33, 34, 35]

The requested IRB proposal would support PI, Co-I, and staff time to execute the project in collaboration with two US Mid-Atlantic and South regions hospice companies.

3. Population:

a. Sample (i.e., target population, age range, study site(s)):

Study site: Johns Hopkins University

Target Population: We will recruit participants from Hospicio Servicios Suplementarios De Salud Inc and Hospicio Luz Celeste in Puerto Rico, Bridging Life Hospice in Westminster, MD and VITAS Hospice in San Antonio, TX. We will recruit current HFCGs who identify as Hispanic or African American, English- or Spanish-speaking, older than 18 years of age and caring for a patient with a cancer diagnosis. If we run into recruitment issues, we will expand inclusion to other hospice diagnosis while still giving priority to HFCGs of cancer patients. We will also recruit hospice physicians or nurse practitioners, nurses, social workers, and chaplains. We will compensate participants with a $50 gift certificate.

b. Does the study include vulnerable populations (i.e., prisoners, adults lacking capacity to consent, pregnant individuals**,** children, non-viable neonates/neonates of uncertain viability, non-English speakers**,** children who are in foster care or wards of the state)?

Vulnerable population: the only vulnerable population included in the study are Non-English speakers HFCGs. Although we will offer intervention to all eligible HFCGs we will attempt to include minority population from the Latino community that are Spanish-speakers and self-identified as Hispanic.

c. Inclusion criteria and Exclusion criteria:

HFCG Inclusion criteria: Self-identified AA or Hispanic family caregivers of cancer patients enrolled in hospice residing at home with PPS (Palliative Performance Scale) [36, 37] score of 20 or better and phase of illness[38] ≤3 that are English or Spanish speakers. Active caregivers must be at least 18 years old and without self-reported cognitive impairment. *Psychiatric history.* We will include HFCGs irrespective if they have or not psychiatric or psychological treatment and psychotropic medications and will collect this data as part of demographic self-reported data.

HFCG Exclusion criteria: non-AA or non-Hispanic HFCG of non-cancer patients who are actively dying with a PPS score <20% or at phase of illness[38] ≥4, not English or Spanish speakers, and receiving inpatient hospice care. Caregivers younger than 18 years or with self-reported dementia, cognitive impairment, or uncontrolled conditions impairing participation. *PPS scale.* In order for HFCG to receive an adequate dose of the intervention patients need to have PPS>20, which reflects a prognosis of at least 17 days.[39] Hence, the PPS provides the specific level of health of patients that we will use to exclude HFCGs.

Hospice staff Inclusion criteria: Employee of hospice agency, older than 18, and part of the patient care team.

Hospice staff Exclusion criteria: Employee from a different hospice agency, younger than 18, a volunteer, or not part of patient care team.

d. Setting: Four hospice agencies from Puerto Rico, Maryland and Texas.

Bridging Life Hospice. Bridging Life Hospice, a nonprofit affiliate of Carroll Hospital, a LifeBridge Health Center, is dedicated to enhancing the quality of life for patients needing end-of-life care, allowing them to live as fully and comfortably as possible by providing quality palliative care, pain and symptom management, and support for their families. We included Carroll Hospice because this hospice serves Baltimore, Carroll, and Frederick counties, Baltimore City, all in Maryland, and Pennsylvania, covering rural, suburban, and urban areas. Their average annual census is 1,641, with 1,030 patients receiving home or facility-based (not inpatient hospice) hospice services. Some 24% of them have a cancer diagnosis; their LOS is 62 days, and ethnicities include African Americans (10%), Asians (0.5%), and Hispanics (0.7%), among others. Based on our prior study, many patients had a college education or higher (52%) compared to elementary or high school (48%). The average household income was approximately $116,971, serving a deprivation index from the least to the most disadvantaged areas.

VITAS Healthcare Hospice in San Antonio, *TX.* We chose VITAS Hospice Company because they serve a large proportion of Hispanic hospice patients and have a long record of research and education. Founded in 1978, VITAS Hospice is one of the largest hospice companies in the US, serving many states and the District of Columbia. VITAS comes from the Latin word for "lives." VITAS is a growing family of hospices providing the highest quality human services, products, and case management to terminally ill and other appropriate patients and their families with measurable advantages for the patient, the family, the medical community, the employee, and the stockholder. While their national office is in Florida, the San Antonio, TX office has agreed to collaborate with our study. Their average annual census is 1975 patients, and 31% have a cancer diagnosis. Their average LOS is 96 days, and ethnicities include African Americans (6%), Asians (1.1%), and Hispanics (41%), among others (52.3%).

Founded in 2015, ***Hospicio Luz Celeste*** is a nonprofit hospice in Caguas, Puerto Rico. Luz Celeste hospice serves rural communities in Caguas, Aguas Buenas, Cidra, Cayey, Aibonito, San Lorenzo, Yabucoa, Naguabo, Juncos, Las Piedreas, Gurabo, Maunabo and Humacao. As of 2024 Luz Celeste hospice had an average daily census of around 162 patients, their LOS is 120 days, 24% have a cancer diagnosis, and serve mainly Hispanic ethnicity patients. They provide comprehensive, compassionate care to people with terminal illness and their families. Their team of professionals and volunteers provides support that addresses all needs—medical, emotional, social and spiritual.

Founded in 1991, ***Hospicio Servicios Suplementarios De Salud Inc*** is a private hospice agency accredited by Medicare and Puerto Rico Department of Health. Servicios Suplementario de Salud hospice serves communities in San Juan, Puerto Rico and other neighboring cities, serving mostly rural (40%) and urban (60%) population. As of 2023 Servicios Suplementario de Salud hospice has an average annual census of around 251 patients, their LOS is 75 days, 33% have a cancer diagnosis, 60% have dementia diagnosis and serve mainly Hispanic ethnicity patients. They provide comprehensive, compassionate care to people with serious illness and their families, including palliative and home care.

4. Methods

a. Study design: Please select one or more categories and provide additional detail as needed:

☐ Research conducted in an educational setting

☒ Survey/interviews (**If the target sample includes children, this study may require expedited review**.)

☐ Educational tests [e.g. cognitive diagnostic, aptitude, achievement] (**If the target sample includes children, this study may require expedited review**.)

☐ Public observations (**If the target sample includes children, this study may require expedited review**.):

☒ Benign behavioral intervention (A benign behavioral intervention must be brief in duration (although data collection may take longer). The intervention must be harmless, painless, and not physically invasive. If the study will include a benign behavioral intervention, please provide **justification/rationale for the intervention to be considered benign/non-significant risk.** (**If the target sample includes children, this study will require expedited review and the eForm A should be used**.):

☐ Research and demonstration project conducted or supported by Federal department or agency for Public benefit or service

This project proposes a two-group randomized trial (N=74) using multiple methods to evaluate NOVELA's preliminary efficacy in reducing caregiving anxiety in AA and Hispanic HFCGs of cancer patients. **We hypothesize that adding this educational intervention to usual hospice care will improve HFCG self-efficacy and knowledge of pain management, thus lowering HFCG anxiety, optimizing caregiving satisfaction with hospice care, and potentially benefiting cancer patient care.**

Study design and procedures per Aim.

Aim 1 will test two hypotheses: (1) HFCGs in the NOVELA intervention will have higher self-efficacy and lower anxiety than HFCGs in the control group. (2) HFCGs in the NOVELA intervention will have a higher level of knowledge regarding pain management than HCFGs in the control group. HFCGs (N=74) will be randomized into either the intervention (receiving NOVELA plus usual hospice care support) or control (receiving usual hospice care support) group.

HFCGs assigned to the *control group* will not be offered telenovela video access and will receive usual hospice care support that consists of an interdisciplinary team approach for EOL care. The hospice team develops a care plan to meet each patient and caregiver's individual needs and usually consists of the hospice physician, nurses, aides, social workers, bereavement, and spiritual counselors.[40]

HFCGs randomized to the *intervention group* will work one-on-one with a trained interventionist to use a web-enabled device (computer, smartphone, or tablet) to access and provide video viewing (3-6 mins) throughout four twice-a-week video conferences using synchronous viewing. An interventionist will greet HFCG, introduce the purpose and topic of the video, facilitate video viewing, then elicit clarifying questions and reinforce the main messages. Each virtual session will be video recorded, with participant permission, to enable monitoring of intervention fidelity and feasibility. We will collect measures with HFCGs in both groups upon consent at baseline and 14- and 30-day follow-ups. Each participant will directly enter data into the REDCap[41 42] software system. We will take an intent-to-treat (ITT) approach to evaluate preliminary efficacy and estimate the effect size of NOVELA. We will use the latest R or similar statistical software for all analyses and reports.

Aim 2 will involve interviewing hospice staff (N=20). We will use NVivo for qualitative coding and analysis.

b. Timeline (from implementation to completion of project)

		Year 1				
	Pre-award	Q1	Q2	Q3	Q4	Post-award
IRB approval						
Stakeholder group meetings						
Recruitment of participants						
Data collection						
Data analysis						
Manuscript submission						

c. Analyses

Quantitative outcomes to be measured include the Caregiver Self-Efficacy Scale,[43,44] Family pain questionnaire knowledge subscale [45] Patient Health Questionnaire 8-item (PHQ-8),[46, 47] and Generalized Anxiety Disorder 7-item scale (GAD-7).[48,49] We will administer these instruments at baseline and 14- and 30-day follow-ups. We will use the GAD-7 scale as a primary outcome, assuming we have two post-intervention surveys from 32 participant (16 in each arm), with a high (conservative) within-participant ICC of 0.5, 90% power, and two-sided type-one error 0.05. These assumptions will yield a design effect of 1.5 and a Cohen's d of 0.88 or higher in the change between follow-up and baseline GAD-7 scores between intervention and control groups. This Cohen's *d* corresponds to a 3.2 point difference, which is more than the reported minimal important difference of 1.5 points[50] (assuming SD of 3.6) [51] between the study groups in GAD-7 anxiety scores[48,49]. With an expected attrition rate of 35%[52], we will randomize 50 participants (25 in each group). Audio recordings from interviews with hospice staff will be transcribed verbatim. Template analysis techniques[53], a method for classifying verbal and behavioral data into categories of similar meaning, will analyze qualitative data using an inductive approach. This analysis will help develop and establish the benefits and opportunities for NOVELA's improvement, as expressed by AA and Hispanic HFCGs and hospice staff.

5. Research Procedures

a. Describe sequence and timing of all study activities. Be sure to distinguish research procedures from those that are part of standard clinical care or curriculum.

Hospice site leaders will generate a weekly list of names of home hospice patients and their caregivers who are currently receiving home hospice care. Site leaders will ensure that caregivers received study flier as part of admission packet and will ensure they have assented to release their names and contact information to Dr. Cruz. This revised list will contain contact information (e.g. name, phone number) of the listed family caregiver along with the name, race/ethnicity and age of the hospice patient for recruitment purposes. Each site leader will transfer this list to Dr. Cruz via encrypted email. A research member will review patient's electronic health record for eligibility and those potential participants will be contacted by phone to informed them about the study. Participants who express interest will provide oral consent and then will be assign to a study group by research staff.

We will execute the randomization scheme via REDCap,[41,42] a clinical trials management software used for randomization and data tracking. A pre-specified block randomized schedule will determine assignment to arm for each participant based on a 1:1 ratio, with a block size of 4. Data manager will oversee the randomization. Randomization will be stratified by hospice site and also by sex and ethnicity of caregiver. Following the consent and completion of baseline measures, the research coordinator will note the HFCG group assignment in REDCap. The research coordinator will inform HFCG participants of the group assignment and trigger the interventionist to initiate intervention activities. All other members of the research team will remain blind to group assignment. Intervention group participants, study coordinator, and interventionist cannot be blinded to group; however, study members involved in outcomes assessment will be blinded.

HFCGs assigned to the *control group* will not be offered telenovela video access and will receive usual hospice care support,

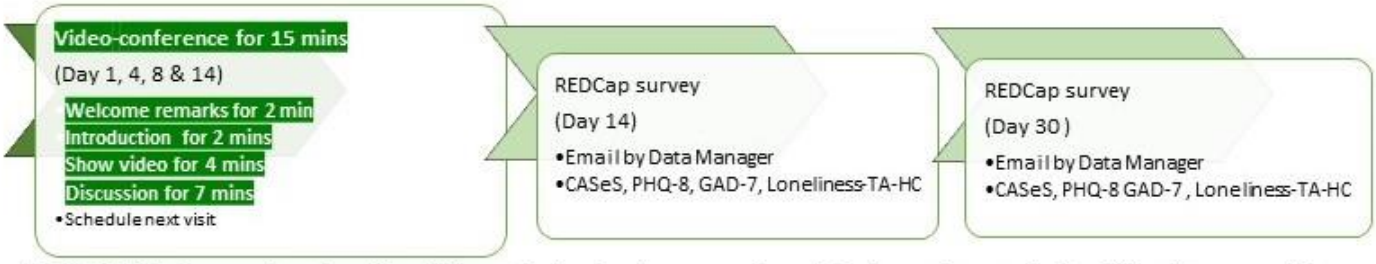

FIGURE 1. Intervention timeline. Video episode duration ranges from 3-6 mins and one episode will be shown per visit.

that consist on interdisciplinary team approach for EOL care. The hospice team develops a care plan to meet each patient and

caregiver individual needs and usually consists of the hospice physician; nurses; aides; social workers; bereavement and spiritual counselors.[40]

HFCGs randomized to the *intervention group* will work one-on-one with a trained interventionist to use a web-enabled device (computer, smartphone, or tablet) to access and provide video viewing (3-6 mins) throughout four twice a week video-conferences using synchronous viewing. Figure 1 shows the intervention timeline and first square describes minute by minute the intervention procedures. An interventionist will greet HFCG and ask phase of illness questions[38] then introduce the purpose and topic of the video, facilitate video viewing, then elicit clarifying questions and reinforce the main messages. Each virtual session will be video recorded, with participant permission, to enable monitoring of intervention fidelity and feasibility. Include how participants are recruited and by whom. We will collect outcome questionnaires from HFCG both groups using a web-based REDCap survey at baseline, 14 and 30 days. Participants will receive a $50 gift certificate at the end of study participation. Table 2 summarizes the research design and data resources by aim.

We will conduct hospice staff interviews to explore ways to integrate *Novela* into hospice care. Therefore, scalability will be assessed at the end of the study based on the results. A complete interview guide is provided in Table 3.

b. If this is a study with students or employees as participants, describe whether the recruiter is in an evaluator position. **(**If directly recruiting participants, for example, email or web post recruitment, please upload the recruitment documents within Section 13, Q 7 of the application).

Our research team will partner with the hospice teams serving these areas to develop culturally appropriate outreach strategies for recruitment. During the admission visit, hospice staff will provide a study flyer to HFCGs regarding their JHU research collaboration to learn how to help HFCGs. We will obtain a HIPAA privacy waiver and use the electronic health record (EHR) to screen all hospice admissions based on study inclusion criteria. Specifically, VITAS Hospice participants will sign VITAS Hospice HIPAA waiver form after assenting to be contacted by JHU researchers. Their EHR will be flagged for chart review to determine eligibility. After chart review hospice staff will send a list of potential participants to research staff via secured email. Research staff will phone HFCGs referred by EHR screening and obtain oral consent. Hospice staff will also be sampled and enrolled as volunteers, recruited by email for phone interviews. During this call, an informed consent form will be read aloud to the participant, and they will be given contact numbers for additional information as well as contact information for the University Institutional Review Board (IRB). The consent form emphasizes that caregivers can discontinue their participation at any time, and that refusal to participate will not affect their relationship to the hospice agency or the quality of care they receive. The consent form is attached to a follow-up email with the link to complete the baseline measures via REDCap.

Table 1. Recruitment scripts

HOSPICE FAMILY CAREGIVERS

Telephone script guide Aim 1 – <u>English</u> version

Hello, this is _____ from the Johns Hopkins University. May I speak with _____?

Your hospice has let us know that you're willing to learn more about the research study we are conducting with family caregivers. It will take about fifteen minutes to talk about this research study. Can I share a bit more about the work we're doing and how you could help by being involved, or would another time be better for you?

Participation in research is always voluntary and whether or not you decide to participate the hospice care that (care recipient name) receives will not change.

Our caregiver research is **funded by the Maryland Cigarette Restitution Fund** and has two goals. The first goal is to **learn more about the unique challenges, emotions, and problems faced by caregivers like yourself.** The second goal is **to investigate the use of telehealth to deliver education and support for hospice family caregivers while caring for their loved one.**

If you choose to participate, you will receive $50 at the end of the study to reimburse you for your time.

Do you have any questions right now about the information I've just gone over?
Do you mind if I ask you questions to see if you might qualify for the research study?

- Are you 18 years old or older?
- Are you Hispanic or Latino(a)? Or Are you Black/African American?
- Do you have internet access?
- We will be video/audio recording the telehealth visits. Would you be willing to let us video/audio record the telehealth visits?

Now that you've learned more about the study, are you interested in being part of this research?

Telephone script guide Aim 1 – <u>Spanish</u> version
Hola, soy _____ de la Universidad Johns Hopkins. ¿Puedo hablar con _____?

Su hospicio nos ha hecho saber que está dispuesto a obtener más información sobre la investigación que estamos realizando con los cuidadores familiares. Necesito unos quince minutos para hablarle sobre el estudio. ¿Puedo compartir un poco más sobre el trabajo que estamos haciendo y cómo usted podría ayudar con su participación, o prefiere que nos comuniquemos con usted en otro momento?

Participar en investigaciones siempre es voluntario. Independientemente de si usted decide participar o no, quiero informarle que los cuidados de hospicio que recibe (nombre de la persona que recibe el cuidado) no se verán afectados.

Nuestra investigación sobre cuidadores está **financiada por la Fundación de Restitución de Cigarrillos de Maryland y tiene dos objetivos. El primer objetivo es aprender más sobre los desafíos, emociones y problemas únicos que enfrentan los cuidadores o familiares de pacientes en hospicio como usted. El segundo objetivo es investigar el uso de la telesalud para brindar educación y apoyo a los cuidadores o familiares mientras cuidan a su ser querido en hospicio.**
Si elige participar, para reembolsarle su tiempo recibirá un certificado de regalo de $50 al final del estudio.

¿Tiene alguna pregunta sobre la información que acabo de revisar con usted?
¿Está bien si le hago algunas preguntas para ver si califica para el estudio de investigación?

- ¿Tiene 18 años o más?
- ¿Es usted Hispano o Latino Americano? O ¿Es usted Afro-Americano?
- ¿Tiene acceso a Internet?
- Grabaremos en video/audio las visitas de telesalud, ¿estaría dispuesto a dejarnos grabar en video/audio las visitas de telesalud?

Ahora que ha aprendido más sobre el estudio, ¿está interesado en ayudar siendo parte de la investigación?

HOSPICE STAFF

Telephone script guide Aim 2 – English version
Hello, may I speak with [insert participant's name]?
My name is [insert name] and I am calling about a research study we are doing in collaboration with the [insert name of hospice agency]. We are conducting a study that involves understanding more about the unique challenges, emotions, and problems faced by hospice staff like yourself.
We would like to provide you with information about this study to see if you would be interested in participating. Your participation would be entirely voluntary.
Would you like to hear more about the study?
If YES, continue.
If NO, thank the person for their time.

The purpose of this study is to investigate the use of telehealth and telenovela videos to deliver education to support (African American/Hispanic) hospice family caregivers receiving home hospice care. Our goal is to gather information from hospice staff like yourself to modify and refine a culturally tailored intervention for integration into hospice care.
If you agree to participate, you will be part of a group of hospice providers who will provide participate in approximately 15-20 minutes phone interviews.
You will receive a $50 gift certificate at the end of the interview to reimburse you for your time.
Do you have any questions?
Answer all questions.
Are you interested in participating?
If YES, will schedule a time convenient for participant and interviewee to meet.
If NO, thank the person for their time.

Email script guide Aim 2 – English version
Subject: **Enhancing Self-Efficacy and Lowering Anxiety Through a Telenovela Intervention for Caregivers of African-American and Hispanic Hospice Cancer Patients*: Pilot Trial*** Recruiting hospice provider participants.
Dear [name of hospice provider]:
We are contacting you to ask for your participation in a research study. We are modifying a culturally tailored educational intervention using telenovela videos to show the symptom-related issues of hospice cancer patients that African American and Hispanic home hospice caregivers may face. For this part of our study, we are seeking hospice providers to participate in a 15-20 minute phone interview to explore ways to integrate this intervention into regular hospice care.
Participation in this research study is voluntary.
If you agree to participate, you will be emailed a $50 gift certificate after the interview.
If you are interested or have any questions, please email dcruzoli@jhmi.edu.
Thank you in advance for considering participating in our research.
Sincerely,
Dulce Cruz, MD
Protocol Number: IRB00457633
Principal Investigator: Dulce Cruz, MD

c. Discuss data collection procedures including measures/assessment tools. [Does the data collection involve audio or audiovisual recording? If recording, please include permission to record language in interview guide or consent script].

Data sources. Table 2 summarizes the research design and data resources by aim.

a) Questionnaires: We will collect questionnaires from HFCG using a web-based REDCap survey. The questionnaires will include measures of demographics, anxiety (Generalized Anxiety Disorder 7-item scale, GAD-7), depression (Patient Health Questionnaire 8-item scale, PHQ-8), Caregiving (CG) self-efficacy (Caregiver Self-Efficacy Scale, CaSES), HFCG pain knowledge (Family pain questionnaire, FPQ knowledge subscale), and Loneliness, Therapeutic Alliance (TA) and Hospice Care (HC). We chose these instruments to measure distinct constructs using the *Novela* theoretical framework. While the proposed set of measures and the schedule are similar to what we used in a proof-of-concept study, to ensure data collection completion we decreased the schedule of measures from 4 to 3 times to be completed 7-10 days after intervention session. Per the pilot participants' report, these measures presented a minimal burden. **Rationale for PHQ-8 instead of PHQ-9.** The 9-item version of PHQ-9, is a self-reported measure of depressive symptoms composed of 9 Likert-type items, each of them corresponding to one of the 9 diagnostic criteria

for major depressive disorder of the 5th edition of the Diagnostic and Statistical Manual of Mental Disorders.[54] An 8-item version (the PHQ-8) has been proposed to avoid possible ethical problems and implications surrounding positive response to the 9th item of the PHQ-9 about suicide and suicidal ideation.[55] Because of the lack of clarity regarding what Item 9 is assessing and because it may identify many medical patients who have had passive thoughts about death or about self-harm, but a relatively small proportion who have actually considered self-harm, the PHQ-8, which omits Item 9, has been proposed for use in medical populations. [56] If the "suicide item" on the PHQ-9 does not accurately assess suicide risk, then using the PHQ-8 will avoid referring for immediate psychiatric evaluation the many patients with passive thoughts of death or self-harm who are not at risk for suicide.[56] Removal of Item 9 has been found to have only a minimal effect on overall scoring. PHQ-9 and PHQ-8 scores correlated at r=0.998 [56] and, despite being a slightly shorter version, the PHQ-8 has shown very similar psychometric properties when compared to the PHQ-9. [47] Although it is a screening questionnaire, the PHQ-8 has proven prognostic ability to identify at-risk groups at the population level. Hence, the PHQ-8 could be a suitable option to be used in studies in which clinical interviews are not feasible, [55] such as our study where we will be using REDCap to collect data via self-report.

TABLE 2. Summary of research design: data sources, schedule, and description by study aim

Specific Aims	**Data Source and Schedule**	**Description of Data & Research question (RQ) or Hypothesis (H) addressed**
Aim # 1 **Investigate the preliminary efficacy of delivering NOVELA to African American (AA) and Hispanic HFCGs of cancer patients.** H1: HFCGs in the *Novela* intervention will have lower mean symptoms of anxiety and depression (primary outcomes) as compared with those in the control group. H2: HFCGs in *Novela* intervention will report higher CG self-efficacy and pain knowledge (secondary outcomes) compared to those in the control group.	Questionnaires –HFCG self-report *At baseline only* *At baseline, 14 & 30 days* *At 14 & 30 days*	DEMOGRAPHICS- (27 items) **HFCG's:** age, gender, sex, ethnicity, race, education, BRIEF health literacy screening[57], marital status, household income, self-reported psychiatric diagnosis or psychological treatment, and psychotropic medication; **Care recipient's:** living location, age, gender, sex, ethnicity, race, education, marital status, and hospice diagnosis. **Caregiving history:** relationship to the care recipient, month/year started caregiving role, #days/week and #hours/day provide care. SURVEYS-(58 items) Generalized Anxiety Disorder 7-item scale (GAD-7)-higher scores reflect higher anxiety. Internal reliability Cronbach's alpha = 0.89. (H1)[48,49] Patient Health Questionnaire 8-item scale (PHQ-8)- higher scores reflect higher depressive symptoms. Internal reliability Cronbach's alpha= 0.89. (H1) [46, 47] Caregiver Self-Efficacy Scale (CaSES) - higher scores reflect higher self-efficacy (21 items, 4 subscales, score ranges 21-84). Cronbach's alpha for all domains is 0.73 - 0.85. (H2) [43 44] Family pain questionnaire (FPQ) knowledge subscale - higher scores reflect higher knowledge of pain (9 items). Reliability= 0.80 Content validity =0.90. (H2)[45] Loneliness, Therapeutic Alliance (TA) and Hospice Care (HC) – three scales for intervention mediators. Loneliness- 1 item with higher scores indicating worse loneliness.[84] TA- 7-items with higher scores indicating higher therapeutic alliance with interventionist.[85] HC- 13 items from the CAPHS survey indicating participant's satisfaction with hospice, communication with team, use of resources and pain management training.
Aim # 2 **Evaluate the benefits of NOVELA as perceived by hospice staff and AA and Hispanic HFCGs of cancer patients.**	Semi-structured interviews of Hospice staff *Throughout the study*	*RQ1: What are the facilitators and barriers to scalability of Novela as perceived by hospice staff?* Hospice staff's perspective on challenges, barriers, and facilitators of integrating *Novela* into hospice care. This information will provide elements for future adaptations needed for a full clinical trial.

b) **Semi-structured interviews:** We will conduct and record semi-structured phone interviews with hospice staff. Each interview will be transcribed verbatim. We developed the interview guide using (1) questions from previous studies[10] with this population about the intervention, (2) implementation science, and (3) input from the study team. The interview will be iteratively adapted to improve the richness of data and quality of answers. Topics will include: hospice staff perceived challenges with integration and scalability. To ensure consistency in interviewing and coding procedures, trained research staff will conduct interviews and transcript coding.

TABLE 3. Interview Guide	
	Questions for Hospice staff
Challenges	What are the challenges you perceived as hospice staff in integrating *Novela* intervention into the home visits?
Integration	-What can your organization do (or what does it need) to be able to integrate the intervention into standard care? -How can the intervention be used in your organization to improve services? What could make the intervention more useful to your organization? -What will motivate a hospice staff to use telenovela videos? In which circumstances do you think hospice staff will use the telenovela videos?
Scalability	In what ways does the *Novela* intervention needs to be modified for implementation?

d. If your study involves data/biospecimens from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies. Please note: Certificate of Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016. If this situation applies, Section 36, question 4 in the application will need to be answered "Yes" and "Hopkins Faculty" should be selected in question 7. No other documents are required.

This does not apply because our study does not involve data from participants enrolled under other studies.

6. Data Management/Security

a. Describe your plan for recording and storing research data.

Participant enrollment will be tracked in a database using Johns Hopkins University (JHU) REDCap that is designed and maintained by Data Manager, and the PI, Dr. Cruz. Similarly, self-report questionnaire data will be collected via the survey software REDCap. Data collected via REDCap is entered on a secure website located behind the JHU firewall. The data collected from this source will be stored on a secure database website with multiple backups created regularly, will not have PHI, and will use participant code number as a subject designator. Paper documents in this study will be limited to participant code list and reimbursement information to be kept separated from research data. These documents will be stored in a double-lock office cabinet and password protected encrypted electronic records inside secured network with limited access to PIs and other trained research team members. Paper research records with subject identifiable data (name and email address) will be stored separately from research records that identify the subject by study code number only.

b. Discuss if the participant data will be de-identified and, if not, how the data will be secured. Is data recorded or links maintained such that participants can be identified, directly or through identifier links? If so, please describe how data will be secured. *Note that SAFE desktop is best for data storage and analysis; JH OneDrive may be used for data sharing among team members/collaborators, but it is not intended for long term storage nor is it configured for conducting analyses.*

Participant data will include assessment measures, video recording of intervention and audio recording of interviews, all of which be coded and kept separate from coding list. Video-recording and interviews transcripts will be revised and de-identified for analysis and data sharing with co-investigators.
Participant information in this study will be limited to participant code list and reimbursement information to be kept separated from research data. The study provides subject reimbursement, which requires only temporary storage of social security number of participants who do not have access to internet. Reimbursement forms will be kept in a locked filing cabinet in a locked office in our locked suite. All subject reimbursement forms will be submitted electronically to a secure drive. The social security number will be removed from the form and securely shredded once the payment has been processed. The social security number will be redacted from any paper copies of the reimbursement forms retained at our research offices. Coded list will be kept in secured network and locked office for at least 10 years, then shredded.

c. Identify who has access to the data.

PIs, Research Coordinator and other trained research team members.

d. Please describe any plans for data dissemination, including but not limited to, any plans to deposit data in external or internal repositories or share individual (person)-level data for publication purposes. Please consult the IRB's guidance on Sharing of Individual Level Research Data and describe how your dissemination plan aligns with these guidelines. Please be specific about the data that will be disseminated (including any tools needed to interpret it) and any methods that will be used to prepare the data for dissemination. If there are no plans nor requirements for individual-level sharing and data dissemination will consist of aggregate or summary-level data in publication, please state so. *If you have submitted a formal Data Management and Sharing Plan for funding purposes, please reference the plan here. These plans should be uploaded in Section 9 Item 4 of your eIRB application.*

The research team supports NIH's philosophy on making findings publicly accessible. Our dissemination plan includes presentations, peer-reviewed articles in multiple disciplines, and making the results publicly available on an accessible website. There is no plans or requirements for individual-level sharing and data dissemination will consist of aggregate or summary-level data in publication.

7. Risks and Potential Benefits

a. Address the risk of loss of confidentiality and/or any other risks.

Hospice family caregivers and hospice staff will incur minimal risk by participating in the study including, information breach, emotional reaction or risk of breach of confidentiality. Informational breach will be minimized by coding participation and keeping coded data in a secured storage (double lock placement and double password protected file) for analysis of study results. Upon consent subjects will be told that audio and video recordings will be used to obtain qualitative data. These recordings will be kept in a password protected file on a secured network with daily back-ups. Once data is transcribed for analysis, transcripts will be de-identified for data analysis and storage. De-identified recordings will be retained for a minimum of 7 years before destruction of recordings. Emotional risk can be associated with discussion that involves a sensitive topic that can trigger an unwanted emotional response (e.g. anger, sadness, crying, among others) and this varies from person to person. In our meeting discussions, we will consider subjects' experiences, culture and environmental setting as well as their reaction to the topic. If requested by participant, additional assistance from hospice agency (e.g. social work or chaplain support and counseling) will be offered after their participation. Potential risks could include frustration or anxiety with malfunctioning or technically deficient equipment. Some individuals entering the study might not know how to use video-conferencing program, which may cause some anxiety or frustration. Participants may feel nervous about discussing their caregiving experiences, as well as their bereavement experiences on this platform. We will continue to minimize these risks by being considerate as we contact

family by phone. We will assure participants, both verbally and in writing that they may withdraw from the study at any time. Finally, hospice staff will not release names of any potential participants to the research team without first obtaining assent that the research staff can contact them. Questionnaires' risk of harm or discomfort while answering questions is minimal given that the probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

b. Discuss the steps you are taking to minimize risks

Caregiver confidentiality and comfort with the technology are protected, for caregivers and hospice staff must agree to participate in the study. Training staff to understand their role in recruiting participants, as well as preventing a breach of their confidentiality will address this concern. All paper forms and recordings will be kept in locked cabinets in locked offices within a locked suite. All computerized data will be stored on password-protected and encrypted computers and networks. Only study personnel with a specific need to use data will be granted permission to access it. Finally, all participant information taken from the home or hospice office will be identified not with names but with an arbitrary identification code. Hospice staff will participate in recorded interviews, and all recordings will be transcribed and stripped of identifying information. All research data that leave the hospice office will be maintained in a locked file cabinet and secure computer in the PI's office.

c. Discuss any potential benefits of the study.

The proposed project has the potential to improve hospice services by improving hospice support of caregivers. This project's aim to develop educational videos that are culturally tailored, will likely result in connecting caregivers with the story and with hospice staff, fostering an environment in which they can obtain additional information and social support that improves active caregiving experiences. On the other hand, participants might not receive a direct benefit but study will inform future research toward that benefit.

8. Payment and Remuneration (Detail compensation for participants)

To motivate study participation and completion, each participant will be provided $50 for their participation.

9. Survey and Interview Study Forms (Upload your survey(s) and/or interview guides in Section 20, Q 2 of the application).

See attachment for demographics, GAD-7, PHQ-8, CaSES and FPQ-knowledge subscale.

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