COVER PAGE

TITLE: **Improving Self-Efficacy Through a Telenovela: Feasibility Study**

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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 provide complete information for each item below. If an item is inapplicable to your research study, explain why.**
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TITLE: Improving Self-efficacy through A Telenovela Intervention for Caregivers of Patients receiving Hospice Care*: Feasibility Study*

1. Purpose/Aims

Telenovela is a television drama or soap opera that can be used to lead viewers to contemplate and discuss critical issues through video storytelling (1). Prior work showed informational telenovelas had a positive effect on Latino family caregivers' attitudes toward end-of-life (EOL) care services (2). The role of videos in hospice and palliative care shows significant promise, underscoring their use as a mode of education for family caregivers that could potentially enhance caregiver's self-efficacy, decrease their anxiety, and reduce burnout. Despite the value of video education, many programs have failed to provide engaging material (3).

Based on input from HFCG, we have produced a bilingual (Spanish and English version) four chapter telenovela video series *(To Care/ El privilegio de cuidar)* as part of NCI funded diversity supplement study.[12] Founded upon extensive preliminary work, *To Care* portrays the journey of one hospice family as they struggle with the hospice decision, pain management, decision-making, and finally the dying process. Averaging only 4:65 minutes, each chapter addresses one of these problems, validating family experiences and identifying potential solutions (See Figure 1). The goal was to develop the telenovela and test its concept for acceptability among (n=39) HFCGs. YouTube Analytics report and semi-structured interviews suggested that when comparing HFCG that viewed traditional videos with HFCG that viewed telenovelas, the telenovela was watched more (longer viewing duration) and caregivers reported more follow up actions and reflection about their own hospice experience. While this gives us data showing acceptability of our telenovela for educational intervention (proof of concept), the delivery was suboptimal and the efficacy could not be evaluated.). Based on this work and interviews with hospice staff we have built an intervention, *NOVELA,* to disseminate telenovelas to family caregivers in hospice agencies. We will test the feasibility of *NOVELA* delivery in the hospice setting and evaluate efficacy of the intervention. The overall expectation is that *NOVELA* will improve self-efficacy thus lowering anxiety in hospice family caregivers. This proposal has the following aims:

- Specific Aim 1: *To pilot test the feasibility and acceptability of integrating NOVELA with hospice care for family caregivers of hospice patients*
- Specific Aim 2: *To investigate the preliminary efficacy of integrating NOVELA with hospice care for family caregivers of hospice patients*

Figure 1. Narrative video: To Care
Based on input from stakeholders, we produced a four chapter telenovela-like video series, *To Care,* which portrays the journey of one HFCG as she struggles caring for her husband who is receiving hospice care.

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)

The theoretical framework for *NOVELA* is adapted from Bandura's model (4) which describes **self-efficacy, as a person's beliefs about their ability to perform a behavior to produce a desired outcome**. In Social Cognitive Theory, perceived self-efficacy to exercise control over potentially threatening events plays a central role in anxiety arousal (5). The anxiety- reduction effects stem from the sense of control because that perceived coping efficacy operates as a cognitive mediator of anxiety. The framework contends that **a specific intervention** will present **information** that **effects beliefs** and impacts specific **outcomes** (See Figure 2). In this case, the telenovela (intervention) uses storytelling to present information about specific caregiving concerns (information), changing caregiver self-efficacy about their care (beliefs) and decreasing caregiver anxiety (outcome). Bandura proposed that perceived self-efficacy (beliefs) influences what coping behavior is initiated when an individual is met with stress and challenges (6). The *NOVELA* intervention comes from a credible source with guided mastery of hospice staff to elicit previous caregiver experience and with video education to provide modeling and persuasion with the potential to change caregiver self- efficacy (5). Social Cognitive Theory establishes a direct link between self-efficacy and anxiety, positing that people who believe they can exercise control over challenges are unlikely to be anxious, whereas those who feel unable to effectively respond to challenges are often highly distressed (5). The telenovela uses a narrative story designed to increase knowledge and the ability of family caregivers to care for hospice patients. We expect that *NOVELA* has the potential to enhance family caregiver self- efficacy and improve caregiver anxiety, which will then reduce patient symptoms, and decrease healthcare utilization by the patient. Results from this study will advance the development of an innovative intervention and will provide fundamental knowledge regarding the pathways through which NOVELA leads to self-efficacy (7) and improved outcomes.

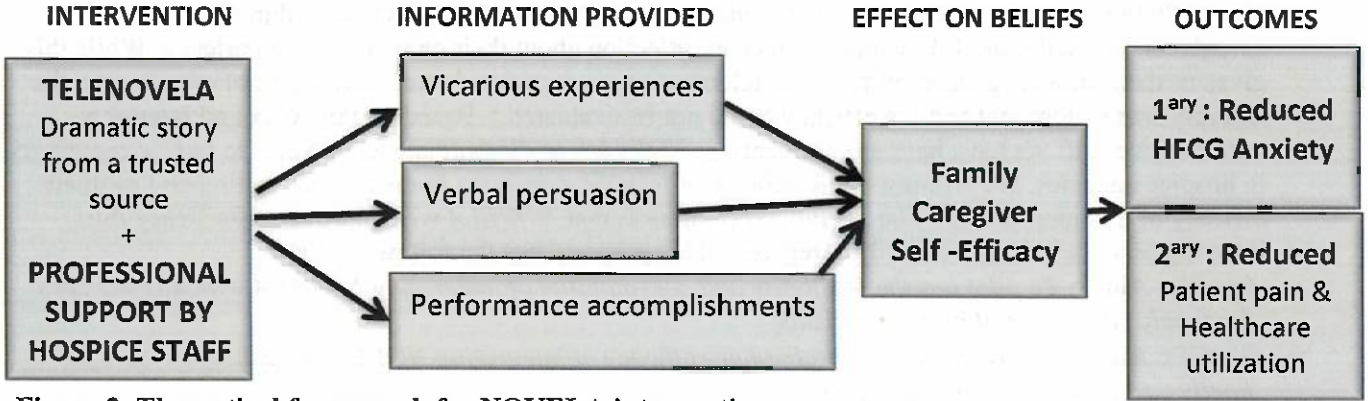

Figure 2. Theoretical framework for NOVELA intervention

The proposed research is significant for three reasons. First, it targets an understudied and often medically underserved population, family caregivers of hospice patients; secondly, it tests an innovative theory-

based intervention to enhance family caregiver well-being; and finally, it identifies health outcomes as a result of the intervention. Results from this study will be significant not only in advancing the development of an innovative intervention but also will provide fundamental knowledge regarding the pathways through which *NOVELA* improves self-efficacy (7) and improves outcomes. Insights into the feasibility and efficacy of *NOVELA* will provide knowledge to researchers, and clinicians, to help identify specific therapeutic strategies to more effectively enhance HFCGs' well-being and thus, impact patient care.

3. Population:

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

Study site: Johns Hopkins University

Target Population and Power Analysis: *Hospice Family Caregivers (HFCG)* – Caregivers will be referred by hospice staff and consented by research staff by phone. Accounting for 35% attrition adjustment, power calculations, conducted by Dr. Budhathoki, estimated a sample size of 55 subjects with an expected 36 participants with outcome data at the end. This will provide more than 83% power to detect the 2-point pre/post minimal clinically important difference (with estimated SD of 4 points for the differences) at the 0.05 level of significance in GAD-7 anxiety scores (9) (10). If the effect size is smaller than 2-point change in the study sample, the statistical test would not be significant.

b. Does the study include vulnerable populations (i.e., prisoners, **adults lacking capacity to consent, pregnant women, 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 HFCG. Although we will offer intervention to all eligible HFCG we will attempt to include minority population from the Latino community that are Spanish-speakers. This will allow us to collect data for purpose of future research studies targeted to this population that is not well represented in the literature.

c. Inclusion criteria: Identified family caregiver of patients enrolled in hospice. Caregivers must be over the age of 18, without cognitive impairment, and with access to wireless device and internet.

d. Exclusion criteria: HFCG of patients that are actively dying. Caregivers younger than 18 years, with cognitive impairment and without internet access.

e. Setting: Three hospice agencies from Maryland, USA.

Gilchrist Hospice company was chosen based on our existing relationships, their interest and willingness to participate in this research, number of annual admissions, length of stay, and proximity to the Principal Investigator. It represents rural, suburban, and urban populations. Founded in 1994, Gilchrist is the largest nonprofit hospice in Maryland. Gilchrist serves the Central Maryland communities of Baltimore City and Anne Arundel, Baltimore, Carroll, Harford and Howard Counties. Gilchrist hospice has an average census of around 953 patients, their LOS is 60 days, 33% have cancer diagnosis, and various ethnicities, including 20% African-American. They provide comprehensive, compassionate care to people with serious illness and their families. Additional programs that Gilchrist offers are Jewish Hospice, Music Therapy, and We Honor Veterans. They have three inpatient centers that offer end-of-life care for individuals with pain and symptoms that cannot be managed at home or in a residential community, or those unable to remain in their homes. Their team of professionals and volunteers provides support that addresses all needs—medical, emotional, social and spiritual.

Seasons Hospice company was chosen because they served a large area of Maryland and their long record of research and education. Founded in 1997, Seasons Hospice is the 5th largest hospice company in the US, operating 29 Medicare certified sites across 19 states and utilizes the highest level of technology available to the hospice industry and many custom proprietary solutions. While their national office is in IL, the Maryland office has agreed to collaborate with our research study. Their average annual census is

485 with 500 patients per day and 24% of them have cancer diagnosis, their LOS is 55 days and ethnicities include African Americans (35%), Asians (1.8%) and Hispanics (1.1%) among others (62%).

Carroll 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. Carroll Hospice was added to test a different recruitment strategy and it serves Baltimore, Carroll and Frederick counties, Baltimore City and Pennsylvania.

4. Methods

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

☒ Survey/interviews (**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 Design and Methods. This application proposes to test the feasibility and potential efficacy of *NOVELA* using a single group pretest-posttest design with repeated measures and mixed methods after the intervention. Our purpose is to look at the intervention in a real-world context to allow evaluation of feasibility in the actual setting. This trial meets the definition of pilot feasibility study because it explores factors needed for a future definitive RCT, including the determination if the intervention is deliverable in-person, and factors associated with treatment adherence and dose. The intervention will be considered feasible with 70% treatment adherence (sessions attended and extent of video views), and 70% completion of anxiety and self-efficacy assessments. Table 1 summarizes research design and data resources by study aim.

Table 1. Summary of research design: data sources, description and analysis by study aim

Aim	Data Source	Description of Data	Analysis	Outcome Variable
Aim 1 *To pilot test the feasibility and acceptability of integrating NOVELA with hospice care for family caregivers of hospice*	Video Recordings of intervention sessions *4-Weekly sessions*	Each session will be recorded and analyzed to examine: number of sessions attended, viewing time in each video, time spent in discussing each video, content of discussion/conversation.	Descriptive statistics Content analysis	Feasibility and fidelity
	Questionnaire *At 14, 30 and 60 days*	Acceptability will be evaluated using an investigator-developed question related to HFCG Satisfaction with NOVELA.	Descriptive statistics	HFCG acceptability

	Semi-structured interviews of HFCG *At end of study*	Family caregiver's perspective on usefulness of NOVELA, attitude, learning, reaction and intention-to-change behavior with videos	Content analysis	HFCG assessment of NOVELA intervention
Aim 2 *To investigate the preliminary efficacy of integrating NOVELA with hospice care for family caregivers of*	Questionnaires – family caregiver self-report *At baseline, 14, 30 and 60 days*	Demographics, Generalized Anxiety Disorder 7-item scale (GAD-7) and Caregiver Self-Efficacy Scale (CaSES)	Descriptive statistics & Repeated measures ANOVA	Demographic variables Family caregiver self-efficacy Family caregiver anxiety

b. Timeline (from implementation to completion of project)

PROJECT TIMELINE															
Timing			1 Year Project											Post	
Activities		*Pre*	*M1*	*M2*	*M3*	*M4*	*M5*	*M6*	*M7*	*M8*	*M9*	*M10*	*M11*	*M12*	*M1*	*M2*
Project Start Up		x	x	x											
Obtain IRB approval		x	x												
Hire and train interventionist research staff		x	x												
Hospice company onboarding		x	x	x											
Finalize REDCAP surveys and processes		x	x	x											
Enroll HFCG (60 days of enrollment)					x	x	x	x	x	x					
Data Collection (baseline, 14, 30 & 60 d)					x	x	x	x	x	x	x	x	x		
Preliminary and complete data analysis								x	x	x	x	x	x	x	x	x
Disseminate findings (i.e. PCRC & AAHPM)											x	x			x	x
Manuscript and Grant writing														x	x	x
Planned accrual = 55																
Target Accrual 10 per month																

c. Analyses

This application proposes to evaluate the feasibility, acceptability, and potential efficacy of *NOVELA*, identifying through semi-structured interviews intervention barriers and facilitators as well as caregiver well-being outcomes (baseline and multiple follow-up self-efficacy and anxiety measures). Mixed methods analysis with explanatory data collection with equal data status will explore challenges of the intervention for implementation and measure theoretically based caregiver outcomes. Insights into the feasibility and preliminary efficacy of *NOVELA* will inform a full scale randomized controlled trial testing the efficacy and translation into hospice clinical practice.

Demographic and background variables will be summarized. Continuous variables will be summarized using means and standard deviation or median and inter-quartile range, as appropriate. Categorical variables will be summarized using frequency and percentages. As this is a pilot study, we will focus on estimating effect sizes and looking at measures of feasibility and acceptability of the intervention. We will evaluate preliminary efficacy in terms of effect size estimation, i.e. pre and a post (a follow-up time point) difference between means for self-efficacy subscales and anxiety score, and 95% CIs of the differences.

Aim 1- Analysis of feasibility and acceptability measures: **Quantitative analysis.** Measures of feasibility and acceptability will be summarized. We will establish clear benchmarks for the measures by which success of feasibility and acceptability will be evaluated (e.g., degree of participation in intervention or number of views or engagement). Specifically, the intervention will be considered feasible with 70% treatment adherence based on number of sessions attended, more than 50% of video viewed, and 70% completion of anxiety and self-efficacy assessments. We will analyze frequency data across the time points. For example, we will compute data completion percentage. Thus, missing data rate is a measure of feasibility in this pilot study. An ordinal measure, e.g. acceptability or satisfaction rating of NOVELA program, will be described using median and inter-quartile range. Engagement will be summarized using means and SDs, and 95% CIs for difference between means will be estimated. **Qualitative analysis.** Video and audio-conferences with HFCG and semi-structured interviews of HFCG will be recorded using Rev.com and transcribed using F4 analyze program. Two researchers will independently code transcripts to sort broad categories determined a priori. In addition to co-coding, trustworthiness process will include a clear audit trail, use peer debriefing and discuss discrepancies to reach consensus. The constant comparative method, which allows analysts to move iteratively between codes and text to derive themes, will guide the identification of themes (13). Thematic analysis of qualitative data (semi-structured interviews) will be used to explore barriers and facilitators of the intervention for implementation and theoretically-based caregiver outcomes.

Aim 2- Analysis of the preliminary efficacy of NOVELA (self-efficacy subscales and anxiety):
Quantitative analysis. We will describe the data to identify any patterns across the time points (baseline and after 14, 30 and 60 days). Those with and without missing data will be compared on baseline variables to determine variables related to missingness. We will group missing data reasons and run frequency distribution. The extent of missing data will be one of the feasibility outcomes. We will impute any missing data. If assumptions are reasonably met, we will run a repeated measures ANOVA. We will not have adequate power to apply more advanced methods of statistical inference; however, we will compute 95% confidence intervals (CI) for difference in means.
All of these analyses together will help us in assessing feasibility and acceptability with a potential of showing efficacy on outcomes such as caregiver self-efficacy subscales and anxiety. That information will be used in planning a larger fully powered randomized controlled efficacy study. We will then use more advanced statistical methods, e.g. mixed modeling, to evaluate efficacy of NOVELA intervention after accounting for confounders, moderators and mediators.

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.

Research procedures: The family caregivers that consent to participate will work with the interventionist to use a web-enabled device (computer, smartphone or tablet) to access and view the telenovela video (one of four episodes, each 3-6 mins) over the course of 4 hospice visits (one episode per visit). All four visits will be in person using telehealth via video-conferencing. The number of visits is based on the number of videos which content is prioritized based on previous work. The interventionist will introduce

the purpose and topic of the video, facilitate video viewing and then elicit clarifying questions and reinforce main message. Detailed of intervention is described in Table 2.Alternatively, if unforeseen situation (i.e. natural disaster) does not permit video conferencing or if caregiver expresses concern with technology in-person or phone visits session will be offered and audio recorded. However, in a pandemic situation only video and phone visits will be offered.

After verbal consent is obtained, participants will receive an email with the consent form and a link to a REDCap survey for web-based collection of baseline measures (GAD-7, CaSES). These measures will be collected at 14, 30, and 60 days. The data collection schedule reflects our desire to have a measure pre-post exposure to NOVELA at two different time points and also close to the patient's death without unduly burdening family caregivers. Our experience shows that 75% of family caregivers were no longer in the study after 90 days due to the death of their patient (average hospice length of stay is 71 days). Research assistants will conduct phone interviews with all family caregivers 14-30 days after their patient's death or completion of study participation. Details about questionnaires are described in Table 1 and 3. Figure 2 shows intervention visit timeline.

Table 2: Script of Intervention
SCRIPT FOR BEGINNING OF VISITS: Hi! How are you doing? Today we will watch a short video about caregiving, but before I share that, I would like to ask you some questions regarding your experience as a caregiver. When taking on a new challenge what experiences of success can you recall? So far what caregiving challenges have you overcome? OR While caring for your loved one what have you done well? (Reinforced that behavior by praising and compliments). Remember that the best way to learn a skill or improve your performance is by practice. In doing so we are teaching ourselves that we are capable of acquiring new skills. We've made four short videos just for this group. They are only about 5 minutes long. Each one shows a different episode of a telenovela. Telenovelas share information through stories—often in a very dramatic way. Our telenovela focuses on Marinela, a woman caring for her husband, Tom, as he receives hospice services. (Depending on initial conversation caregiver or Interventionist chooses video chapter. Interventionist shares via videoconferencing telenovela video. The following order of chapters can vary depending on HFCG needs)
SCRIPT AFTER WATCHING THE VIDEO: Do you have any question about the issues shown in the video? OR What is your reaction to this episode? *WEEK 1: In this week's episode, Marinela struggles to come to terms with Tom's diagnosis. Tom and Marinela talk with their hospice nurse, Ricardo, and learn more about hospice. Tom and Marinela's daughter, Betty, steps in to help her family.* PROBES: What do you see going on in this video? How does Marianela and Tom's experience relate to your life? How do these videos inform your understanding of the role of hospice *WEEK 2: This week's episode addresses pain. Marinela isn't sure what is going on with Tom and calls the hospice nurse, Ricardo, for help. Ricardo teaches Marinela how to know if Tom is in pain even if Tom cannot speak.* PROBES: What is your favorite character or any other aspect of this week's episode? Tell us about how do you know if your loved one is in pain. How might you enhance or fix the situation if it were your experience? *WEEK 3: In this week's episode, Marinela makes an important decision to call hospice instead of 911 when Tom appears to be in pain. Then, Marinela and the hospice nurse work together to decide how to treat Tom's pain. This is an example of shared decision making.* PROBES: What are your reactions to this episode? How do these experiences relate to your life? Do you feel like you are a part of the decision-making process with your hospice team?

WEEK 4: This week's episode takes us through Tom's final journey: the dying process. This episode also provides tips on helping a loved one during the final days and hours. It discusses four messages that often matter most at the end of life: "Forgive me." "I forgive you." "Thank you." "I love you." PROBES: Did this video help you better understand what to expect as your loved one is nearing death? What phrases do you feel would be most important to share with your loved one as they are dying? How might you lean on your support network during your loved one's final days?
SCRIPT FOR END OF VISITS: What was the most important thing you learned from the video this weeks? or Did you learn anything new from this video? If so what? (Finalize with a line summarizing main message of the video and emphasizing HFCG learning point.)

Figure 2: Intervention Timeline

b. Include how participants are recruited and by whom.

Recruitment/Consent: Using recruitment strategies that have proven effective in our prior research (15) (16) (17), hospice admission staff will screen eligible participants in compliance with privacy and confidentiality regulations, and briefly explain the study. If an eligible participant is interested and gives consent for a research staff person to contact them, a phone (orientation) session will be scheduled by the research staff in order to go over the study in detail (See Table 3 recruitment scripts), and obtain verbal consent to participate in research activities. 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.

A second research strategy will be introduced to obtain better study accrual and decrease hospice staff burden. Five days after hospice admission, during which time potential participants will receive brochure with information about our study, patient's chart will be access to screen for eligibility for our study (PPS>20%). Potential referrals or candidates' information will be retain separately in an encrypted electronic file. Eligible participants will be contacted by phone by research staff for oral consent. Once participant's provides oral consent then their information will be transferred into REDCap. Information of those participants that decline consent will be kept until the end of study in a separate encrypted electronic file for recruitment strategy purposes. The reason to keep the data is to avoid calling potential participants more than once. After study ends such data will be permanently destroyed.

Table 3. Recruitment scripts

HOSPICE STAFF SCRIPT: Our agency is collaborating with researchers at Johns Hopkins University to learn how to help hospice family caregivers. Will you opt out of being contacted by research team? Thank you!

RESEARCH STAFF SCRIPT: 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 we are conducting with family caregivers. You received a flyer about the study during admission but we know that visit is pretty overwhelming and you may not remember seeing or hearing about the research. It takes about fifteen minutes to talk about the 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? May I please audio record our call for Dr. Cruz's review?
Participation in research is always voluntary and whether or not you decide to participate I want to let you know that the hospice care that (care recipient name) receives will not change
Our caregiver research is **funded by the National Institute of Nursing Research** 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?
Now that you've learned more about the study, are you interested in helping by being part of the research?

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 Measures: For specific information on measures relative to study aims see **Table 1.** Measures will include video recordings of intervention visits, semi-structured interviews of HFCGs and 3 instruments (See details in Table 4). There are a total of 40 items for data measures. Schedule of measures will be as follows: At baseline will include 40 items (CaSES, GAD7, and demographics); at 14, 30 and 60 days will be 29 items (CASeS, GAD7, and Satisfaction).

Table4. Psychometric properties of instruments

Instrument	Description	Psychometrics (reference)
Generalized Anxiety Disorder (GAD-7) Primary outcome	A 7-items, scale 0-3, score range 0-21, which measures anxiety. Has been used with hospice caregivers (3, 4).	Reliability= 0.89 (5)
Caregiver Self-Efficacy Scale (CaSES)	A 21-items, scale 1-4, score range 21-84, which measures self- efficacy with 4 subscales. Instrument developed for caregivers with advanced cancer (6).	Reliability = 0.73 - 0.85 (7)
Satisfaction question	One-item Likert scale 1 (not satisfied)-5 (very satisfied), score range 1-5, question regarding HFCG satisfaction with NOVELA.	Does not apply because this is an investigator-developed question

Data Collection: Below is the detailed information of data collection.

1) Video Recordings of Intervention Visits: we will record interventionist weekly sessions with HFCG. To facilitate HFCG personal interaction with interventionist, all four sessions will be delivered via video conferencing and video recorded. Alternatively, if unforeseen situation (i.e. pandemic or natural disaster) does not permit video conferencing or if caregiver expresses concern with technology (i.e. lack of internet access) in-person or phone visits session will be offered and audio recorded. Data will be analyzed to examine fidelity (e.g. dose and delivery efficacy) and feasibility of intervention (e.g. data completion rate, sessions attended, extent of video views, and time of video discussion). The fidelity plan is based on the NIH Behavior Change consortium (11). We will address fidelity based on **design** (the intervention is theory-based), **training** (we will develop an intervention manual for the purpose of interventionist training which will be finalized at the completion of the study). In addition, we will provide personalized feedback based on the audio and video recordings from this pilot, **delivery** (extent of video views and sessions attended), **receipt** (study visit duration and discussion time to determine intervention engagement), and **enactment** (participants will discuss with interventionist questions regarding video topics and intention-to-change behaviors will be explored in exit interview). During weekly study team meetings, the interventionist and study team will discuss study visits, review content and opportunities to improve intervention fidelity.
2) Questionnaires: We will collect measures with families upon consent (baseline,) 14, 30 and 60 days. The data collection schedule reflects our desire to have a measure close to the patient's death without unduly burdening family caregivers. Our experience showed that 75% of family caregivers were no longer in the study after 90 days due to the death of their patient (average hospice length of stay is 71 days). Research specialist will send a REDCap survey via email. Demographic data include the date of admission to the home hospice program, patient and family caregiver age, gender, marital status, ethnicity, education, hospice primary diagnoses, and relationship to the patient. Measures for this study are three questionnaires. GAD-7 was chosen because this was the instrument used on diversity supplement study and it has evidence for validity, sensitivity and specificity in detecting anxiety (9) (10). CaSES was chosen because is the only instrument developed for caregivers with advanced disease with adequate reliability and validity (12). Lastly, caregiver satisfaction question using a 5-point Likert scale to measure HFCG reaction to NOVELA was chosen for simplicity and to avoid HFCG overburden with questionnaire.
3) Semi-structured Interviews: Finally, 14-30 days after their patient's death or completion of study participation, each caregiver will be invited to participate in a semi-structured phone interview to provide feedback on their research experiences and the intervention components they received. Questions for the interviews will be developed by PI and collaborator, then reviewed by PCRC Caregiver's core panel of experts. Topics will include: video attitudes, learning, usefulness, identification, intention-to-change behaviors and feelings about caregiving with NOVELA. (See Table 4 Interview guide). All interviews will be recorded and transcribed.

Table 5. INTERVIEW GUIDE	
Attitudes	**1.**What are the benefits perceived with the use of telehealth to deliver videos for caregiver health education during hospice care? **2.**What are the challenges perceived with the use of telehealth to deliver videos for caregiver health education during hospice care?
Learning	**3.**What was the most important thing you learned from the videos? Did you learn anything new from the videos/video-conferences? If so what?
Usefulness	**4.**Were the videos useful for you? Which one(s) were the most helpful? **5.**Was the discussion of the videos useful for you?
Identification	**6.**How do the experiences of the videos relate to your life? **7.**Did you identify with any of the characters? Any favorite character?
Intention-to-change behavior	**8.**How might you lean on your support network during your loved one's final days? **9.**Did you share your experience of the videos with anyone? If so with who?

Caregiving Anxiety & Self-efficacy	**10.**Did the study change the way you feel about caregiving? If so how? **11.**What changes in your level of confidence/comfort regarding caregiving you noticed because of participating in the study? **12.**What changes in your level of anxiety/worries regarding caregiving you noticed because of participating in the study?
Intervention & Incentive	**13.** How was the timing of our visits together? How often you suggest we continue offering these visits (more often (every 2-3 days) or less often (weekly)? **14.**At what point of your caregiver trajectory you think these visits are most helpful (before, during or after hospice care)? **15.**What incentive you suggest we provide for caregivers in the future (gift certificates, training, etc.)

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.

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 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. The Data Manager is responsible for managing the software, database, and website. 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 PI 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. As part of the NIH data sharing directive, de-identified data from this study will be transferred to the PCRC De-Identified Data Repositories.

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.

Participant data will include assessment measures, video recording of meetings and audio recording of exit interviews, all of which be coded and kept separate from coding list. Video-recording fidelity checklist and exit interviews transcripts will be revised and de-identified for analysis and data sharing with grant sponsor, PCRC (Palliative Care Research Cooperative group). Transfer of de-identified data to the PCRC Data Repository will occur one year after completion of the award or after findings are published.

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.
The de-identified data that are collected and entered will remain in the PCRC Data Repository indefinitely. These data could be used for future research studies or distributed to another investigator for future research studies without obtaining additional informed consent from you or your legally authorized representative. . The PCRC fully supports the Final NIH Statement on Sharing Research Data, and will assist all investigators and study personnel to ensure their compliance. Consistent with OMB Circular A-110 and subsequent NIH Grants Policy Statements, the PCRC will provide access to all de-identified data collected as part of PCRC-supported investigations, insofar as access is consistent with IRB/CHR rules, local, state, and Federal laws and regulations, and the HIPAA Privacy Rule.

c. Identify who has access to the data.

PI, Data Manager and other trained research team members.

7. Risks and Potential Benefits

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

Hospice family caregivers 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 monitor the intervention. 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 HFCG, additional assistance from hospice agency (e.g. social work or chaplain support and counseling) will be offered after the video conference. 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. Also, the potential for frustration exists in that study personnel will have an initial phone meeting (orientation) at the beginning of the study as well as communicate with them by phone at the point they become bereaved. We will continue to minimize these risks by being considerate as we contact family by phone. We also 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 consent 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 must agree to participate in the study's video-conferencing program. 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 patient/family information taken from the home or hospice office will be identified not with names but with an arbitrary identification code. HFCGs 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 use of technology (telenovela video) connects 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.

Subjects may learn from interventionist and the telenovela video how to better perform self-care, patient pain assessment and management and what the final days may look like. The main message of the telenovela video is: *While caring for a loved one with terminal cancer*.... 1-The most important thing you can do is accept help and company. 2-Focus on a different fight, fight the pain and other symptoms. 3-Listening is the last sense they lose, so talk to your loved one. Also, hospice staff may increase their referral to service sources to help decrease caregiver burden and increase caregivers satisfaction, knowledge and positive attitudes towards hospice care. 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 HFCG participant will be provided $50 honorarium and bereavement cards when appropriate, for a total cost of $2750. Hospice will receive participation honorarium by paying registration cost for one hospice staff member to assist a Maryland Hospice and Palliative Care Network (HPCN) annual conference, for a total cost of $1200 under consultant cost expenses.

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

See attached (4 documents: Demographics, Satisfaction, CaSES & GAD-7). Also attached is the Data collection sheet.

JOHNS HOPKINS
MEDICINE

Office of Human Subjects Research
Institutional Review Boards

1620 McElderry Street, Reed Hall, Suite B-130
Baltimore, Maryland 21205-1911
410-955-3008
410-955-4367 Fax
e-mail: jhmeirb@jhmi.edu

Date: December 29, 2021

CHANGE IN RESEARCH APPROVAL

Review Type:	Expedited
Principal Investigator:	DULCE Cruz-Oliver
Number:	IRB00256812 / CIR00076168
Title:	Improving Self-efficacy through A Telenovela Intervention for Caregivers of Patients receiving Hospice Care: Feasibility Study
Committee Chair:	Susan Bassett
IRB Committee:	IRB-X

Date of Approval: December 23, 2021

Date of Expiration: September 11, 2023

The JHM IRB approved the above-referenced Change In Research.

Approval includes change in estimated length of study; change in study team members (addition of Mari Bugayong); revised eIRB application sections (General Information, Study Team Compliance Training)

IRB review included the following:

Use of an oral consent process.

Johns Hopkins Study Team Members:

This approval includes study team member changes. See below for a list of approved study team members.

There is an institutional policy which governs the participation of post-doctoral fellows in research. Please see: http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/post_doc.html. You are responsible for ensuring that any post-doctoral fellows on the study team meet all criteria for participation pursuant to this policy.

Gabrielle Milner, Martha Saylor, Nowella Durkin, Tom Smith, Katie Nelson, Chakra Budhathoki, Marcela Blinka, Kelsea Mensh, Mari Bugayong