IRB Approved Protocol

Title: Faith-Based African American cancer Survivorship Storytelling: A culturally relevant intervention to alleviate psychological stress

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Emory IRB Protocol

Title: Faith-Based African American cancer Survivorship Storytelling: A culturally relevant intervention to alleviate psychological stress. Short Title: Faith-Based African American Cancer Survivorship Storytelling

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B. Significance. African Americans continue to experience the highest overall cancer mortality rates, more advanced staged cancers [1], and higher levels of psychological distress from cancer than non-Hispanic Whites [2 3]. Additionally, cancer patients and family caregivers (FCGs) also experience high levels of psychological distress which has been linked to unmet needs for support and information from health care providers [4]. African American patients and FCGs attribute the root cause of their psychological distress to overwhelming anxieties and concerns that cancer will lead to suffering, death, and isolation for their family member diagnosed with cancer [5-7]. When interviewed, patients and FCGs recall images and horror stories of African American cancer patients who "suffered and died," after a period of "wasting away" and in excruciating pain [7]. The stories available to patients and FCGs are often replete with memories of a family member who waited too late and subsequently died from a cancer that spread to the point where treatment would not be effective [6,7]. Despite high levels of psychological distress, African American patients and FCGs are not likely to seek mental health services [8] or to participate in support groups [9]. African American cancer patients and FCGs report being receptive to interventions that incorporate cognitive and religious strategies [7], yet these interventions lack conceptual clarity and are rarely tailored for diverse populations [10].

Faith-Based African American Cancer Survivorship Storytelling

The use of storytelling in interventions is emerging as a beneficial method for improving health outcomes among minority [11-13] and low literate populations [14]. In research among African American populations, storytelling interventions have resulted in increased health promoting behaviors such as adherence to follow-up care and quality of life among breast cancer patients [15], increasing self-care among diabetic patients [16 17], and improvements to blood pressure [18]. interventions that incorporate dimensions of spirituality in group discussions may not have lasting effects [19] while health educational interventions delivered in faith-based institutions exclude those not religiously affiliated [20]. However, the more troubling issue is the lack of conceptual clarity among spiritually-based interventions and the assumption of cultural equivalence in the design of these studies [10].

On the other hand, storytelling that incorporates the narrative of religious songs to overcome psychological distress in life-threatening is interwoven into the culture of African Americans [21-23]. Additionally, in the U. S., African Americans are the most religiously affiliated population and likely to conceptualize their spirituality as a certainty that a Higher Power (God)

exists [24] and that this sacred being has the ability to protect, heal, and deliver them from the evils and sufferings of their worldly existence [25]. The outward expression of this spirituality has primarily been expressed through African American storytelling and religious song which has and continues to be an important aspect of their religious culture [25,26]. Moreover, during life-threatening situations, the narrative of these religious songs are used to encourage a positive sense of self through an identity as a child of God, to express a belief and faith in the promise of a life free of pain and suffering [23 25,26], and to promote social relationships among naturally occurring family networks [27]. Despite this strong cultural heritage of storytelling through religious song narrative, healthcare providers and researchers have yet to fully embrace and incorporate this coping strategy into supportive care interventions for cancer patients.

Theoretical Framework. The development of the *Faith-Based African American Cancer Survivorship Stories Intervention* will be guided by concepts in Stress and Coping Theory [28] and Transportation Theory (TT) [29,30]. Stress and Coping theory has been used to examine mental health promiting strategies among African American cancer patients [31,32]. According to this theory, when an event is perceived as stressful, individuals use strategies to affect the stressor or to change the perception of the stressor [28]. Among African Americans, spirituality has been a dominant strategy to change the perceived threat of cancer as an emotion focused strategy [33,34]. Transportaton Theory (TT) has been useful in examining the influences of narratives on health promoting behavior change among African Americans [18,29,35], to promote cancer screening behaviors [12,36,37] and adherence to cancer follow-up care [38]. TT posits that a change in attitudes and behaviors is enhanced through the identification and emotional engagement of a viewer with the narrative. Therefore, the selection of stories incorporated into this intervention considers: 1) similarity to and identification with narrators in the recordings; and, 2) the emotional engagement of participants with selected recordings. Using this combined framework, the final selection of recordings for the intervention will consist of those most likely to influence positive affective (decrease psychological distress) and behavioral changes (engage in supportive social networks) among the targeted population.

C. Goals/Aims: The proposed study addresses a need to integrate spirituality with cancer care as requested among African Americans from the PI's previous research [1,20]. In the PI's research with African Americans, a dominant mental health promoting strategy used in response to a cancer diagnosis is the use of religious stories and songs [8,12]. African Americans have a strong cultural history of relying on religious stories and songs to overcome oppression and mental suffering encountered in their lived experience [9,25,26]. If successful, the findings from this preliminary study will contribute to the evidence that spirituality is important to cancer care and to achieving optimal patient outcomes among this medically underserved population. More importantly, the infusion of spirituality in cancer care has to potential to reduce the high levels of psychological distress experienced among African Americans and their FCG's [21,22]; to enable them to become more engaged in their cancer care [20] and in supportive family relationships [23]; and, ultimately to improve the overall quality of life for African American cancer patients and their FCGs [24].

To achieve our overall goal of improving health outcomes for African American cancer patient/FCG, the following aims will be achieved:

Aim 1: Develop a series of professionally edited narrative video recordings of African American cancer patient and FCG survivorship narratives that are grounded in the strong spiritual culture of African Americans. The recordings will be professionally edited to capture the essence of patient/FCGs describing the psychological stressors encountered, and spiritually-based strategies used to in response to the psychological distress experienced, and mental health outcomes.

Aim 2: Evaluate the usability and acceptability of this intervention. Usability is evaluated through clarity, persuasiveness, and ease of use. Acceptability will be evaluated through enrollment, participation, and concepts of Transportation Theory (identification, engagement, and emotional response).

The work in Aim 1 and 2 is expected to provide sufficient preliminary data to support a future feasibility study that rigorously evaluates a faith-based storytelling intervention incorporating narratives from religious songs that address the psychological distress among patients and FCGs. The greater impact of this intervention is to reduce mental suffering and, assist the African American cancer patient and FCG to engage in supportive relationships during the diagnosis and treatment for cancer.

1. **Study Design:** The proposed feasibility study uses a quasi-experimental (pre-post test, repeated measures) design and qualitative methods to: 1) determine feasibility and acceptability, and 2) estimate effect sizes for outcomes of (psychological distress (primary outcome), spiritual well-being, patient-physician communication, supportive family relationships, and quality of life (secondary outcomes) of the Faith-Based African American Cancer Survivorship Storytelling Intervention among African American cancer patients and their FCGs. Qualitative methods will allow us to explore the influences of concepts from SCT and Transportation Theory on acceptability and satisfaction with the intervention. Specifically, we will use open-ended interviews to explore influences of identification, engagement, and emotional response to components of the intervention. A qualitative descriptive design [36] including content analysis [37] will be used to analyze data obtained from open-ended interviews**.**

2. **Study setting and sample.**
   a. Setting. The study will be implemented in partnership with the outpatient oncology unit at the Grady Cancer Center for Excellence (GCCE). The GCCE is located within the Grady Healthcare System which is a public hospital with nearly 600,000 patient visits each year. The majority of revenues generated through Medicare and Medicaid reimbursement. The Georgia Cancer Center for Excellence (GCCE) at Grady was established by the Georgia Cancer Coalition as part of an initiative to build a statewide network of people and organizations to provide exceptional cancer treatment for all Georgians. *In 2015, GCCE provided care to 1308 cancer patients (674 men/630 women).*

   b. Population to be studied: For this feasibility study, we will recruit a total of 40 dyads with

a recent cancer diagnosis. Patient inclusion criteria captures patients (age 30-89 years) with 1) newly diagnosed with any stage cancer; 2) treatment plans to include weekly outpatient chemotherapy; 3) previously screened and with greater than 0 level of psychological distress; and, 4) willingness to participate in all study activities including data collection; 6) willing to identify a FCG (immediate or extended family member) to participate. Participants will be excluded if they have completed surgery with no plans for chemotherapy; if they find conversations around religion or spirituality emotionally upsetting; if completed more than half of prescribed chemotherapy treatments; or, in hospice care. We will also exclude participants not able to provide informed consent. **FCG (immediate or extended family member) Inclusion Criteria are:** 1) 18 years or older; 2) able to provide informed consent; and, 3) willingness to participate in study activities including data collection. FCG's will be excluded if they find conversations around religion or spirituality emotionally upsetting.

c. Sample size justification: Since this is a feasibility study, our aim will be to compute effect sizes that will guide power calculation for testing intervention effectiveness in a future RCT. Preliminary power calculation indicated that group sizes of 40 dyads (total sample 80) will achieve 80% power to detect a minimum difference of 0.6 in a repeated measurements design having a Compound symmetry covariance structure (standard deviation of 1, within subject correlation of 0.2, and an alpha level of 0.05 assumed).

d. Recruitment efforts: The success of our recruiting efforts will be dependent on developing and maintaining collaborative relationships with personnel at clinic sites. The PI has already obtained the support of GCCE Medical Director, Deputy Director, Social Worker, and Administrator. In addition, during the start-up phase of the study, we will make informal presentations about the study to center clinicians and also presentations at formal protocol start-up meetings with clinic personnel. These steps are important to introduce the study, make clinicians and staff more knowledgeable about the objectives, eligibility criteria, and logistics of the study and gain their support.[133] We have devised a process for working with physicians and nurses and other practitioners in the clinic setting that facilitates accrual of patients into clinic studies. A major concern of clinic personnel is disruption in the flow of the clinic. The PI will meet regularly with clinic personnel to cooperate with and adhere to policies for accessing patients and to ensure that our recruiting efforts do not become burdensome for clinical staff. Clinic staff will be asked to assist with identifying patients diagosed with a recently diagnosis of cancer. We will also review charts to confirm type cancer, stage of cancer, type and duration of planned treatment, and psychological distress screening scores.

e. Field Methods: Research participants will be required to participate in intervention activities and 5 data collection interviews (1 optional open-ended interview). Interviews to complete both open-ended interviews and quantitative measures will take approximately 45 minutes. The actual administration of the intervention (viewing of video recordings) will take approximately 30 minutes with all sessions to occur over a 3-week period.

Participants will be asked to complete interviews at baseline (time of enrollment into study), after each intervention session, and at 6 weeks. These time intervals will allow us

to identify the factors and strategies that affect health outcomes over time and serve to provide preliminary data to support a larger test of the intervention. These points will also allow for comparisons with other long-term investigations of psychological distress among cancer patients.[135-137] At baseline data collection we will collect demographic characteristics of participants including age, gender, education, marital status, occupation, employment status, religious affiliation, proximity to family, type and stage of cancer, type treatment, date of diagnosis, date of treatment, and psychological distress screening scores. All data collection will be conducted by phone or video conferencing platform. There will be an 6th optional open-ended interview after the interview sessions to further explore sources of and expressions of distress among participants.

Demographic and clinical characteristics. For patients, we will collect data on psychological distress levels (the NCCN Distress score [45] from patient records and the Hospital Anxiety, Depression Scale (HADS) [46,47]), type and staging of cancer, and type of cancer treatment by either chart review or self-report. For patients and FCGs we will collect information on age, gender, education level, health status, religious affiliation, religiosity, insured status, income, and geographic residence. The religiosity scale measures frequency of using spiritual practices such as the use of religious songs, reading religious materials, and, attending church. Collection of data for demographic and clinical characteristics will occur immediately after obtaining informed consent and before viewing the video narratives.

NCCN Distress Scale (National Comprehensive Cancer Network) is a well-known screening tool for distress [45]. In the GCC, this tool is administered to all newly diagnosed cancer patients. This screening tool is a thermometer on which patients rate their distress on a level of 0-10 with 10=extreme distress and 0=no distress. The NCCN-DT will be obtained from patient records to determine eligibility for this study. We will only recruit patients with a NCCN-DT score of ≥ 4 which is likely indicative of high levels of distress [48,49].

Psychological distress levels for cancer patients will be measured with the Hospital Anxiety, Depression Scale (HADS) [47]. The HADS is a 14-item self-report scale for anxiety and depressive states for patients [47,50-52]. Internal consistency with African American oncology patients has ranged from .77 (Anxiety) and .78 (Depression)[53]. The HADS is sensitive to change after integrative therapy interventions with scores for Anxiety (8.20±4.34 to 5.79±3.64); Depression (5.97±4.00 to 3.96±3.23) [54]. Scoring for the Anxiety and Depression Subscales of the HADS is (0-21); Normal (0-7); Borderline Abnormal Case (8-10); and Abnormal Case (11-21). Patients and family caregivers will be asked to complete this evaluation at baseline and after all of the intervention sessions.

Quantitative Assessment of narrative quality (narrative characteristics, identification, transportation). Assessment of narrative quality (narrative characteristics, identification, and transportation) will be examined using the Narrative Quality Assessment Tool [55]. Narrative characteristics will be examined using a 9 item scale that measures perceived likability of characters in the story, emotional relevance of the storyline, and cultural elements of the stories [55]. Identification will be examined using a 8-item scale that measures the degree to which participants are able to relate to the characters in the video recordings or perceive their story to be similar to their own [55]. Transportation (engagement) will be examined using a 6-item scale

that measures participants emotional connections to the stories in the video recordings[55]. Response options will be on a 5-pt scale and similar to that in other questionnaires in this pilot (1=not at all to 5=quite a bit). Internal consistency for the three scales range from .92 - .95 respectively [55]. Validity was determined through hypothesized factor structures (CFA) [55]. Patients and family caregivers will be asked to complete these evaluations after each intervention session.

Qualitative exploration of usability and transportation will occur after each weekly intervention session. During the qualitative assessments, participants will be asked to express their thoughts, feelings, and opinions of the narrators and describe perceptions of similarity to, identification with narrators in the recordings, and, transportation (engagement) of participants to selected recordings. *Participants and FCG's will also be asked to describe ways in which they might use the strategies from the video recordings to cope with their own cancer experience.* Guided by Transportation Theory [30] [29], the final selection of recordings will consist of those with higher levels of narrative quality. These stories from actual patients and FCG's and used in this intervention are hypothesized to be relatable and acceptable in content and context. In previous storytelling interventions among African American and Latino populations, *listening* to culturally relevant stories resulted in changes in attitudes and behavior change [56] [13]. We will qualitatively assess usability through perceived navigation (ease of use); content (video length, topics covered, presentation); persuasiveness (mood, encouragement); and, value (time spent, future use, potential recommendations to others. **Description of Intervention:** The intervention will consist of participants viewing a selection of video recorded vignettes during 3 weekly sessions. There will be 5 vignettes included in each session with each vignette edited to a real time of 3-4 minutes (each session is 30 minutes). Since the intervention is designed to be self-administered, there will be a video recorded introduction and instructions for use narrated by the PI. The vignettes are of actual African American cancer survivors narrating stories of ways in which hymns can be used to overcome their *anxieties and depressed moods through the use of a hymn. The hymns included represent exemplars from the 5 themes prevalent in the PI's previous research (see Table 2).*

Intervention Group. In this preliminary study, the intervention will consist of *3 weekly sessions* (each session occurs over 30 minutes duration) delivered to the patient and FCG during an outpatient chemo infusion visit. In the **first step**, the RA/PI will review again purpose of the intervention and follow-up data collection. **In step two**, the patient and FCG will be given a link and password to Vimeo video sharing platform to view preselected video recordings representing the 5 categories of hymns. Immediately after each session, the RA/PI will conduct a short open-ended interview with participants to determine participant identification, engagement, and emotional response to the recordings. We will also explore experiences with use of hymns as a coping strategy. This data will assist with the further refinement of the intervention for a future RCT. **In step three,** we will schedule times for subsequent intervention and data collection sessions.

Informed Consent Process: The PI will read the consent form by phone or video conference platform unless participants would prefer to read it her/himself. Participants will be permitted to discuss the study with family or friends and ask the PI questions. Once the verbal consent form has been reviewed (or read to participants) the research participant will be asked to express their understanding of the consent form. Participants will be asked to describe their understanding of the study to ensure comprehension of the study. Research subjects will be given a copy of the verbal consent form for their records.

6. **Potential Risks/Discomforts to Study Participants and measures to prevent occurrence:**
    a. The risks for injury or bodily harm are minimal since the topics to be discussed are those that typically occur during day to day interactions among family and friends and community (faith-based) groups. A similar study in a southern population has been previously conducted with no known medical risks. Some participants were tearful during their interviews when talking about their illness experience and the support that gave them strength and comfort when anxious or sad but they did not want to stop the interview. Many participants reported that the interview permitted them to discuss a stressful life event they had previously not shared with anyone else.
    b. A select number of participants will be asked to contribute their stories to be included in the larger test of the intervention. Participants that agree to share their stories will be informed of the nature of any disclosure of their illness and other aspects of their stories. Stories from interviews with participants concerned about employment/future employment, reputation, or financial standing will be kept confidential.
    c. Risks that would be associated with loss of privacy or breach of confidentiality. Participants will be informed that it may be possible for others to identify them should their stories be used in a future research study. However, any names, addresses or statements to identify third parties mentioned will be deleted.
    d. Steps taken to minimize the risks. This research consists of a preliminary study to test the feasibility and acceptability of an intervention using hymns to alleviate psychological distress. Discussions of favorite hymn used in response to stressful life events are a frequent part of public conversations among African Americans. Persons who become increasingly distressed or emotionally upset during the interviews will be encouraged to contact their physician for referral to mental health counseling. Efforts will be made to minimize respondent burden during the interview. The PI is sensitive to verbal and nonverbal expressions of fatigue such as squirming, looking around, gazing out the window or simply stating they are too tired to finish. Participants who say they are too tired or are otherwise not able to complete the interview once started, will be given the option of withdrawing or rescheduling their appointment.

7. **Benefits:** One potential benefit to individuals participating in the study is that respondents may receive comfort and/or spiritual uplifting and seek the support of others after viewing these narratives that include religious based songs and text. No other direct benefits to individual participants are likely. The benefit to health services practitioners, on the other hand, is great. Acknowledging, documenting, and describing the nature of religious based songs that help comfort older African Americans through times of adversity will facilitate the development of intervention strategies specific to African Americans but also likely in other cancer populations attempting to cope with chronic illness and/or life-threatening disease. Effective intervention strategies, in turn, will improve the overall well-being of individuals living with such illnesses.

8. **Compensation for time and effort:** Participants will be given $30 for each completed interview not to exceed $180.

9. **Data Analysis: Data Management and Monitoring**:

a. To maintain confidentiality of the data, each participant will be assigned a subject identification number. The subject identification number will be used to keep track of recorded interviews and transcribed data. Identifying information associated with the

subject identification numbers will be kept separate from the data at all times. Digitally – recorded interviews and hard copies of transcribed interviews will be kept on a password protected computer. Data files of transcribed interviews and a database with the research participants' information will be kept on a secure server that can only be accessed by authorized personnel with valid user id and password.

b. *The PI and RA will* complete research training on responsible conduct of research (RCR) using the Collaborative Institutional Training Initiative (CITI). Data and back-up data (study and PHI) will be maintained in separate databases on the team's password-protected database and server as described above. Data will be entered via (Research Electronic Data Capture (REDCap)), a secure web-based application that supports data capture and management for research studies. REDCap data entry also assists in efficient project management and data analysis. Demographic data will also be entered into the Winship Oncore System. Data collected from open-ended interviews will be audio recorded and transcribed and checked for accuracy. All audio-recorded interviews will be immediately uploaded onto a password protected computer for later transcription and analysis. Interviews will be deleted from audio recording devices once data is uploaded onto password protected computers. Interview data will be maintained on password protected computers.

10. Plans for analysis, statistical and/or otherwise:

a. Data analysis will occur on a password protected computer and data stored on servers provided by Emory University.

b. Specifically, we will use structured and unstructured interviews to explore influences of identification, engagement, and emotional response to the intervention. We will also explore qualitatively participant experiences with the use of hymns as a coping strategy.

Statistical software: SAS v9.3 will be used for all quantitative statistical analyses. Quantitative descriptive analyses will be used to describe the baseline characteristics, interrater reliability, and frequencies and rankings of evaluations of video recorded narratives among study participants. The chi-square and Fisher's exact tests (cells smaller than five) will be used to determine differences in the participant responses to the video-recorded narratives according to gender (male vs. female) and patient vs. family caregiver.

Atlas.ti will be used to manage and analyze qualitative data. A qualitative descriptive design [59,60] using open-ended semi-structured interviews and qualitative content analysis [61] will be used to elicit and analyze patient and FCG response to transportation.

Aim 1: Develop a series of professionally edited narrative video recordings of African American cancer patient and FCG survivorship narratives that are grounded in the strong spiritual culture of African Americans. The recordings will be professionally edited to capture concepts of Stress and Coping Theory and include content of patient/FCGs describing the psychological stressors encountered, and faith-based strategies used to in response to the psychological distress experienced, and health outcomes. The selection of video recorded narratives for the pilot test will consist of those that capture a complete story (stressful cancer experience, faith-based coping strategy used, and health outcome) and deemed to have appropriate sound and visual quality. We will also review the final selection to ensure characters in the video recordings vary by age, gender, and type cancer.

Aim 2: Pilot test for usability and evaluation of transportation. A combined quantitative and qualitative methodology will be used to examine transportation of the video

recorded narratives. For evaluation of transportation, we examine means and frequencies to scales responses for narrative quality assessment: similarity to and identification; narrative engagement; and, the emotional engagement. We will use percentiles to rank the selected video recorded narratives. Narratives with higher levels of rankings (top 50%) will be retained for future feasibility testing.

Qualitatively, data from the open-ended interview questions related to usability and evaluation of transportation identity, engagement, and emotional response will be transcribed verbatim and uploaded into Atlas.ti for analysis. Guided by principles of conventional content analysis [61,] each participants' responses to the open-ended interviews will be organized according to categories that emerge from the data. Specifically, we will analyze interview data for *usability*: participant responses to perceived navigation (ease of use), content (video length, topics covered, presentation), persuasiveness (mood, encouragement), and value (time spent, future use, potential recommendations to others. We will also qualitatively explore interviews for transportation: similarity to and identification; narrative engagement; and, the emotional engagement of participants to selected recordings. We will use interrater reliability to validate themes emerging from the data [62].

Guided by principles of conventional content analysis [61], each participants' responses to the open-ended interviews will be organized according to categories that emerge from the data. Codes will be assigned to words or text followed by grouping and categorizing these codes into meaningful clusters. Finally, we will develop definitions for each category/theme with a table representing the definition and an exemplar for themes from the data. We anticipate that these categories will capture the characters/narrators they more frequently identify with, find similar to themselves, perceive as engaging, and elicit positive emotional response. We will also explore data for participant explanations for ranking of recordings. *We will use this data to further edit the video recordings for a future feasibility test*.

10. **Training of study team:**
    The PI or RA will conduct all interviews and will have completed CITI training at Emory.

11. **Plans for monitoring the study for safety**:
    This study is no more than minimal risk.

12. **Confidentiality**:
    All interviews will be conducted by telephone or video conferencing platform. To maintain confidentiality of the data, each participant will be assigned a subject identification number. The subject identification number will be used to keep track of recorded interviews and transcribed data. Identifying information associated with the subject identification numbers will be kept separate from the data at all times. Digitally – recorded interviews and hard copies of transcribed interviews will be kept on a password protected computer. Data files of transcribed interviews and a database with the research participants' information will be kept on a secure server that can only be accessed by authorized personnel with valid user id and password. Identifiers to the data will be destroyed once data is analyzed, published. However, the PI will retain identifiers to data of participants who have given written consent for the interviews to be used in future testing of this intervention.