A Community Developed, Culturally Based Palliative Care Tele-Consult Program for African American and White Rural Southern Elders with a Life Limiting Illness

Study Protocol & Statistical Analysis Plan

NCT 03767517

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APPENDIX I: STUDY PROTOCOL

A Community-Developed, Culturally-Based PC Tele-Consult Program for African American and White Rural Southern Elders with Life Limiting Illness

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Phase III Clinical Trial

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I. Overview

The triple threat of rural geography, racial inequities, and older age hinders access to high quality palliative care (PC) for a significant proportion of Americans. Rural patients with life-limiting illness are at very high risk of not receiving appropriate care due to a lack of health professionals, long distances to treatment centers, and limited PC clinical expertise. Although culture strongly influences people's response to diagnosis, illness and treatment preferences, culturally-based care models are not currently available for most seriously-ill rural patients and their family caregivers. Lack of sensitivity to cultural differences may compromise PC for minority patients.

The two major public health consequences of these problems are:

1) Access-Rural patients have sub-optimal or no access to PC. Despite significant nationwide growth, access to PC is grossly inadequate for the 60 million US citizens who live in rural or non-metropolitan areas. There is low PC use in rural and minority populations. As a result, rural patients experience significant suffering from uncontrolled symptoms that PC expertise could alleviate.

2) Acceptability-Even when palliative and hospice services are available, African Americans (AA), compared to Whites (W) are more likely to receive medically-ineffective, poor quality care due to a culturally-insensitive health care system and mistrust of health care providers. Making culturally competent PC available for diverse underserved and rural Americans is a national priority.

Our community-developed, culturally based tele-consult intervention, specifically targets the gaps of PC access and acceptability. It was developed by and for rural, Deep South AA and W patients and providers, and uses state-of-the-art telehealth methods, to provide PC consultation to hospitalized seriously-ill patients and family. Using National Consensus Project guidelines, and the culturally-based, community-developed PC Tele-consult intervention, a remote PC expert conducts a comprehensive PC patient assessment, in collaboration with local providers. Following interdisciplinary PC team review, the remote clinician communicates recommendations. Two additional structured follow up contacts at Day 3 and 6 ensure care coordination and smooth transitions that enable patients to receive guideline concurrent PC in their communities.

Almost three decades after the Institute of Medicine's landmark report, "Approaching Death" their revised report, "Dying in America," continued to document that hospitalized patients with serious illness are experiencing unnecessary suffering from uncontrolled symptoms. This occurs disproportionally in rural and minority citizens, especially those in the Deep South. Our study will move the field forward by testing a promising culturally-based tele-consult intervention that is scalable, and was developed by and for the community it will serve.

II. Aims of the Study

The aims of this study are to compare a robust, culturally-based tele-consult program to usual hospital care to:

a. **Primary Aim**: Determine whether a culturally-based PC tele-consult program leads to lower symptom burden in hospitalized AA and W older adults with a life-limiting illness.
b. **Secondary Aim**: Determine whether a culturally-based PC tele-consult program results in higher patient and caregiver quality of life, care satisfaction, and lower caregiver burden at Day 7 post-consultation, and lower resource use (hospital readmission, emergency visits) 30-days post-discharge
c. **Exploratory Aim**: Explore mediators and moderators of patient symptom and caregiver burden outcomes.

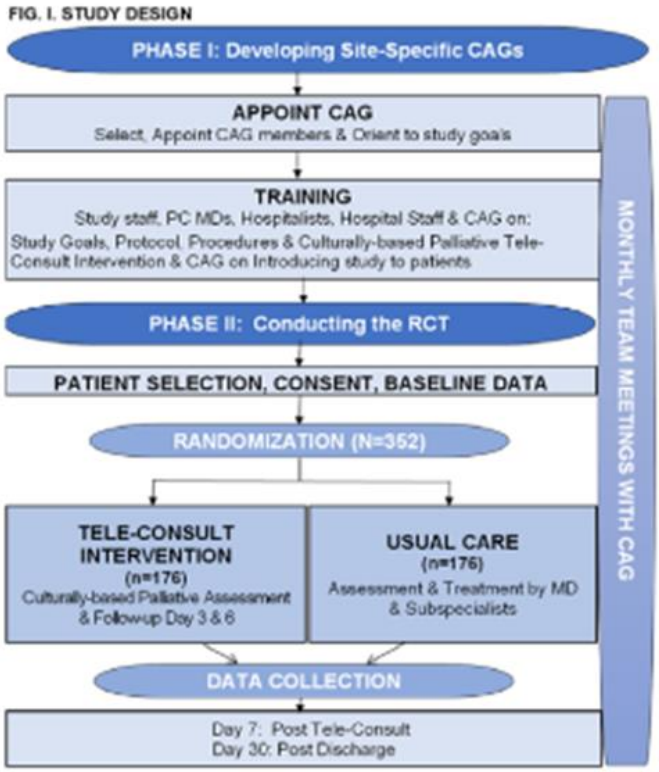
III. Study Population

The hospitals chosen for this study represent typical rural hospitals in size and population representativeness of many of the underserved facilities in the Deep South.

a. **Russell Medical Center, Alexander City, AL**: Russell Medical Center is a not-for-profit, acute care facility serving the needs of east Central Alabama. It is a general medical and surgical hospital in Alexander City, AL, with 80 beds. Survey data for the latest year available shows that 24,827 patients visited the hospital's emergency room. There are 67 physicians affiliated with the hospital, and the hospital had a total of 3,245 admissions. Its physicians performed 835 inpatient and 3,264 outpatient surgeries. Russell Medical Center also expounds upon community health education services through health screenings, support groups, childbirth classes, self-help programs, and athletic trainers to multiple sports teams in its service area.
b. **Highland Community Hospital, Picayune, MS**: Highland Community Hospital is a 60-bed not-for-profit hospital and affiliated clinics provide access to a broad range of quality services, supporting the community and enhancing the level of care for the residents of Picayune MS and the surrounding areas. There are 100 physicians affiliated with the Highland Community Hospital. Its community outreach includes classes and events in different themes including community education, continuing education, screenings, support groups etc.
c. **Aiken Regional Hospital, Aiken, SC**: Aiken Regional Medical Centers, located in Aiken, South Carolina, is a 245-bed acute care facility offering a comprehensive range of specialties and services. The medical staff includes over 900 skilled healthcare/support professionals, a medical staff of more than 120 multi- specialty physicians, and a team of 230 volunteers. The center provides nearly 50 specialty services through its acute care facility, behavioral healthcare hospital and the cancer care institutes of Carolina. Its services reached in Aiken and its surrounding communities. There are different types of the community outreach in Aiken Regional Medical center, including classes, seminars, support groups, or information about new services.

IV. Study Design

This study consists of 2 phases:



Phase I Convening & Soliciting CAG Participation in study design. This phase will consist of assembling CAG members to review study procedures and some CAG members will be trained to approach potential study participants. Potential CAG members (8, with equal numbers of AA and W) will be identified by the hospital staff and community leaders of each of the three sites, and invited to participate in the CAG. Potential CAG members will include respected members of the community, those who have recently lost a loved one and understand end of life care, and community leaders. Potential members will be discussed by the recruiters with the study PIs to ensure there is socio-demographic balance, and equal representation of African American and White members, to ensure all will feel comfortable participating and contributing, and to ensure that they are not all from the same family/church/social group. Following this step, a formal written invitation will be extended to those selected, followed by a phone call by the Study Manager.

Phase II Conducting the RCT. In Phase II**,** we will conduct a randomized controlled trial (RCT) at the 3 sites to test the effectiveness of this innovative program. We will recruit 352 hospitalized AA and W adults over age 65 whose treating physician would not be surprised if they died within the next year and the patients' family/friend caregiver. Half of the patient participants (N=176) will be randomized to receive usual care appropriate to their illness. Patients randomized to usual care in each of the three participating hospitals will receive inpatient care appropriate to their illness. This includes assessment and treatment by the admitting physician, along with any subspecialists that are consulted. The formulation and sharing of prognostic information and the engagement of patients and families in establishing goals of care will be according to the standards of the admitting physician and subspecialists. Treating clinicians may include hospitalists, nurse practitioners, social workers, pastoral care, and occasionally, the patient's primary care practitioners who have hospital privileges.

The other half of the patient participants (N=176) will receive the culturally-based palliative care consult. Patients in the intervention group will receive usual care as described above, and, in addition, will participate in a standardized, comprehensive palliative care Tele-consult

assessment as well as a follow up by the palliative care physician on Day 3 and 6 following the initial consult.

Recruitment Estimates by Hospital

Participating Hospital	no. beds	Annual Admissions	Observed Eligible Patients* (annualized)	Estimated Annual Consults**	Annual recruitment assuming 50% refusal (range of observed - estimated)
Aiken Hospital, SC	243	3767	264	188	132-94
Russell Hospital, AL	80	1506	240	109	54
Highland Hospital, MS	33	1200	296	51	148-25

*Hospitals estimated eligible patients based on study eligibility criteria
**CAPC estimates of consults based on 5-7% of annual admissions

V. Study Duration and Timeline

Enrollment: September 2019 [Anticipated]
Primary Completion: January 2023 [Anticipated]
Study Completion: September 2023 [Anticipated]

Study Timeline **Subject to Change**

	2018				2019				2020				2021				2022				2023			
ACTIVITY	Sept.	Oct.	Nov.	Dec.	Jan.	Apr.	Jul.	Oct.	Jan.	Apr.	Jul.	Oct.	Jan.	Apr.	Jul.	Oct.	Jan.	Apr.	Jul.	Oct.	Jan.	Apr.	Jul.	Oct.
IRB approval																								
Build relationships with hospital staff, orient to study & eligibility criteria																								
PC MD training in culturally-based tele-consult																								
Establish CAG, provide orientation & training																								
CAG quarterly meetings																								
Patient enrollment																								
Data collection																								
Data analysis																								
Progress reports/final reports																								
Presentations and publications																								

VI. Inclusion and Exclusion Criteria

Patient Inclusion Criteria:
(1) AA or W;
(2) > 65 years old; has a condition which fits into one of 3 illness paradigms (including: cancer, cardiac disease, pulmonary disease, neuro-degenerative disease, renal disease, stroke, sepsis, hepatic disease)
(3) Clinician answers "no" to question: "Would you be surprised if this person died in the next 12 months?"
(4) Patient has a caregiver who has been involved in their care.
(5) Able to complete baseline interviews.

Patient Exclusion Criteria:

(1) Unable to complete baseline interviews;
(2) Currently receiving hospice care;
(3) No family member/caregiver.

Caregiver Inclusion Criteria:
(1) Age ≥21 years
(2) English-speaking
(3) Community-dwelling
(4) Not a "sitter"

VII. Randomization Plan

The randomization scheme will be executed via REDCap, a clinical trials management software program. Participants will be randomly assigned to group (1:1) using a computer-generated program overseen by Dr. Kennedy. The randomization scheme will be stratified by site (SC, AL, MS) race (W, AA), and illness trajectory. As the Central Coordinating Site, UAB will manage the randomization process. The UAB study manager will be alerted to the assignment by REDCap and will trigger the local unblinded study coordinator to communicate assignment to the participant and initiate study protocol. All other members of the research team will remain blind to group assignment and participants will be instructed not to discuss their assignment with the local study coordinator collecting the outcome assessments.

VIII. Community Advisory Groups (CAGs)

The community advisory groups (CAGs) will be an integral part of the study. A CAG will be formed at each of the three study sites. Each CAG will be made up of eight members, with equal numbers of African American (AA) community members (four), and White (W) community members (four). Potential CAG members will be identified by hospital staff and community leaders and will include respected members of the community, or those who have recently lost a loved one and understand end of life care.

The role of the a CAG members on the study is three-fold:
a. Advisory: CAG members will be invited to meet with the study team members and PC physicians every three months throughout the study, hear about progress, and challenges, and provide advice when problems arise. The last meeting of this study will be a full report-back and summary to the CAG.

b. Cultural recognition: CAG members will meet with and be trained by the CAG members from Beaufort, South Carolina, who developed the pilot study. We anticipate that the appreciation for and recognition of the southern rural African American or White culture by this study, and a recognition that the community has been instrumental in creating a program that could benefit their community, will result in an appreciation for the potential value of this study.

c. Introducing patients to the study: The CAG member will be the first to meet potential study participants (regardless of which group they get randomized to) to introduce them to the study, and will introduce the CSC. CAG members will be the first to meet potential study participants (regardless of which group they get randomized to) to introduce them to the study. The role of the CAG member in meeting with patients is primarily to make the patient and caregiver feel at ease, and to help build trust. In the pilot study, we found that if an African American CAG member met with an African American patient and caregiver, it helped to address feelings of mistrust in the research study. Particularly helpful was that the pilot CAG members assured patients and caregivers of their belief in the study, and their confidence and trust in the palliative care (PC) physician. CAG members will receive gas cards to cover their travel expenses to and from the hospital.

Before study recruitment begins at the hospital site, the coordinating study coordinator will create a CAG member schedule and telephone tree, to determine which CAG members will be 'on call' each day, and the best way to reach them. This will facilitate the quick action needed to meet with potential study participants after they have been identified and permission has been granted.

IX. Patient Recruitment and Consent Process

Each site will have two part-time study coordinators: a) Coordinating Study Coordinator (CSC) and b) Blinded Study Coordinator (BSC).

Consent Process:

a. Approaching the patient and family: The CSC will screen admissions each weekday and will only approach potential study participants after confirming eligibility (e.g. "surprise question") and getting approval from the treating clinician.

b. CAG and CSC meet with patient and family: Following approval, the CSC will contact the CAG member "on-call" for the day to speak with the patient. The CAG member and CSC will approach the patient. The CAG member will introduce themselves and the CSC, and describe the study to the patient. The CAG will emphasize their role in developing the study and how this study was designed to help the community. If the patient indicates that he/she would like to participate, the CSC will provide an overview of the study, including a description of palliative care, the tele-consult equipment and process, (if randomized to that group), and randomization using a simple visual diagram. (These materials were developed by the R21 CAG and will be reviewed and adapted by each hospital-specific CAG). The CSC will then read the consent form to all patients (assuming no or limited literacy) unless the patient prefers to read it themselves. The family member is invited to participate and will sign a separate consent agreeing to complete questionnaires regardless of group assignment. The CSC will assist the patient (and separately the family member) to complete the baseline questionnaires using an electronic tablet that connects directly to the REDCap database. Baseline data are collected prior to randomization, so study coordinator blinding is not necessary.

The CSC will screen, obtain consent and organize the tele-consult. The CSCs will remain in daily contact with hospital staff and participate in tem meetings to remind clinicians about eligibility criteria. Team meeting attendance will allow the CSC to clarify the study goals and protocol and to strategize solutions if challenges arise. The BSC will collect all data following patient randomization.

X. Description of Tele-consult Intervention

Tele-consult Intervention. The tele-consult intervention consists of 3 interactions between the remote palliative care physician/interdisciplinary team (IDT) and the local patient/caregiver and hospitalist/treatment team.

Community-developed, Culturally-Based Inpatient Teleconsult- Intervention				
Contact #	**When**	**With Whom**	**Method**	**Purpose**
#1 Palliative Care Tele-consult	As soon after randomization as possible	Patient (family) referring hospitalist & remote palliative clinician Local Study coordinator Remote IDT Members	Secure tele-consult Remote IDT review eHR document	1. Conduct community-developed, culturally based palliative assessment. 2. IDT review 3. Develop recommendations & palliative care plan
#2 Follow up Day 3	Within 3 days post consult	Remote & local clinicians	eHR document Telephone	1. Provide recommendations & care plan 2. Respond to patient, family & remote team questions 3. Identify community care team & initiate referrals as needed (including primary clinician/hospice provider if appropriate).
#3 Follow up Day 6	Within 6 days post consult	Remote Clinician Patient/family & local community care team members	Telephone	1. Reassess patient and care plan 2. Assess adequacy of discharge plan or home experience 3. Refer to community resources

Contact #1: the Coordinated Study Coordinator [CSC] will work closely with the patient/family, local team, and remote palliative care physician to determine a time suitable (within 48 hours on weekdays) to perform the Tele-consult. The CSC and the hospitalist/a member of the treatment team will be in the room with the patient and family. The CSC will set up the HIPAA protected telehealth laptop next to the patient's bed, introduce the patient to the remote palliative physician, and the tele-consult will proceed. All Tele-Consults are digitally-recorded within the secure portal. Most consults take 45-60 minutes. To ensure a comfortable conversation with

minimal interruptions we have instituted several steps including checking with floor nurse, putting up signs on the door, and tasking the CSC with running interference in case of interruptions.

Within 24 hours of conducting the Tele-consult, the remote palliative physician will seek an interdisciplinary team review, develop the plan, and make recommendations, which may include immediate patient care (e.g., symptom relief) and continuing care, related to the hospital stay and following discharge. Recommendations may also include referrals to other supportive resources such as a hospital social worker or pastor. The written consult will be documented using a standardized note template that corresponds to the 8 NCP palliative care domains and will be provided via a secure HIPAA-compliant portal that will be part of the patients' inpatient medical record. As needed, verbal contact will also occur between the palliative care physician and the hospitalist staff.

Contact #2 Day 3 (approximately 24-48 hours after first contact). The CSC will arrange a follow up videoconference between the remote palliative care physician and patient if in hospital or via phone if the patient has been discharged. The purpose of this second contact is to determine how patient is progressing, if the plan was implemented, if hospital staff/patient has encountered any challenges or questions, and to determine who will be assuming the patient's care in the community. Documentation of the contact will be provided as described above.

Contact #3 Day 6 (post consult) (via videoconference if patient is in hospital, via phone if discharged.) To determine if patient is experiencing new or ongoing challenges, to confirm availability of community or hospice care as appropriate.

Tele-consult Intervention + Usual Care. In the usual care group and the intervention group, a study coordinator at each site will administer questionnaires to the patient and their designated family/friend caregiver, in person or telephone (if patients are discharged during the study period) at baseline (T1), Day 7 (T2) and Day 30 after hospital discharge (T3). (Study coordinators administering T2/T3 assessments will be blinded to study group- aka Blinded Study Coordinators [BSC]).

Table 5. Measures and Data Collection Schedule

Construct	Instrument & Description	# of Items	T1 Baseline	T2 Day 7	T3 Day 30
Demographics	Demographic Questionnaire- Age, gender, race/ethnicity, marital status, religion, education, occupation, insurance status, financial status.	10	X		
Primary Aim					
Symptom Burden	**Edmonton Symptom Assessment Scale (ESAS)** - symptom intensity using visual analog	9	X	X	
Secondary Aims					
Patient and Caregiver QoL	**PROMIS Global Health -10**. Evaluates physical, social, and emotional health in healthy & chronically ill adults	10	X	X	
Family Satisfaction with Care	**FamCare** - family satisfaction with availability of care, physical & psychosocial care, information giving	20	X	X	
Patient Satisfaction with Care	**Feeling Heard and Understood** - Self-report quality measures for palliative care settings on Likert scale (1 item)	1	X	X	
Caregiver Burden	**Montgomery Borgatta Caregiver Burden Scale (MBCB)**-subscales objective, subjective, demand burden	14	X	X	
Resource Use	**Hospital admission, ED visit, hospice**	NA			X
Exploratory Aim					
Mediators	Consult recommendations implemented by Hospitalist & Pt	NA		X	

XI. Statistical Analysis Plan

Demographic variables (e.g., age, sex, race, disease) will be summarized and compared across treatment groups using t-tests and nonparametric Wilcoxon signed rank tests for continuous measures (age), binomial tests (sex, race), and chi-square statistics for categorical variables (e.g., marital status, education). All demographics and stratification variables found to differ across treatment groups will be included in regression models (referred to as the vector $ZZii$ in the regression models to follow); however, race will be included in the final models separately from the vector $ZZii$ vector. Tabulations of binary and categorical variables will be presented for all measures and broken down by treatment group. Age will be summarized by mean and standard deviation for all participants, and broken down by treatment group.

XII. Data Management Plan

Study coordinators will securely manage all data and PHI in accordance with HIPAA and IRB regulations, and maintain data confidentiality and anonymity. The only physical study document that will contain identifiable information will be the informed consent document, which the study coordinator will store in a secure, locked location until it can be securely transferred to a locked cabinet at the University of Alabama at Birmingham (UAB). All other study documents will only contain the patient's UID, but no identifiers.

The CSC and BSC will transmit all study documents to Dr. Kennedy, the study statistician, for data analysis. This includes questionnaires, fidelity checklists, data collection sheets, spreadsheets, and any other data collection instruments and tools.

a. Spreadsheets

Each CSC and BSC will maintain a number of spreadsheets and documents to track all aspects of data collection at their respective sites.

Referral spreadsheet

One spreadsheet should track potential patient referrals. No identifiable information should be included in the spreadsheet. The spreadsheet should include the following:

• Referral number (e.g., 'referral 001')
• Date of referral
• Name and title of person making referral (e.g., 'Nora, nurse')
• Patient age, ethnicity, sex
• Patient diagnosis
• Name of treating clinician
• Whether or not treating clinician's permission was granted
    - If no, why not?
    - Date of treating clinician's permission/denial
• Whether or not patient enrolled'
    - If no, why not?
    - Date of patient's enrollment/non-enrollment
    - If yes, patient UID

UID spreadsheet/linkage log. The linkage log will be the only spreadsheet that contains PHI/identifiable patient information. It will contain the patient's UID, patient's name, caregiver's name, and phone numbers. This spreadsheet should be password encrypted, and shared only with members of the study team.

Implementation of PC recommendations spreadsheet. The PC recommendations and implementation spreadsheet will track each patient consult using the patient UID. It will contain a list of each of the PC recommendations, and whether or not each of the recommendations was implemented by the treating clinician(s).

b. Fidelity checklist

The CSC will fill out the fidelity checklist for each PC consult, to track the PC physician's adherence to the cultural guidelines. The fidelity checklist will contain the patient UID, the date, and the duration of the PC consult.

c. Data collection sheet

The CSC will fill out a data collection sheet for each patient (both Group A and Group B), using patient's UID. The data collection sheet will record:

- Demographics
- Diagnosis
- Readmissions
- Study group
- PC recommendations
- Family implementation of PC recommendations (determined via family interview)

d. Questionnaires

The DSC will send completed questionnaires (either hard copies of electronic copies) to Dr. Kennedy for analysis. Each questionnaire will only have the patient UID, and no identifiable information.

XIII. Confidentiality/Privacy Considerations

Information obtained about the patient/caregiver will be kept confidential to the extent allowed by law. However, research information that identifies the patient/caregiver may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

• The UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.

• National Institute of Nursing Research/NIH/DHHS

• The Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, the patient/caregiver's identity will not be given out. All study documents and data sent electronically via HIPAA compliant system will be stored in a secure, locked file cabinet at the University of Alabama at Birmingham (UAB).

XIV. Study Risks and Discomforts

This study has very low risk to participants. Risks that they potentially incur include:

a. **Emotional distress:** Talking about their illness and symptoms may cause emotional distress for patients or caregivers. Patient may get tired while answering the questions with the study coordinator. If a patient gets too tired, we can come back later in the day. Sometimes people feel embarrassed or uncomfortable when being asked questions so patients/caregivers can refuse to answer any question.
b. **Loss of confidentially:** There is a chance that people not associated with the study will see patient/caregiver answers to questionnaires. Patient/caregiver name and other identifying information will be removed from study documents. Data will be kept in locked files in the study research offices at UAB. All data will be housed in a secure, password protected database at UAB.
c. **Burden and benefits:** There is a risk related to being placed into a group by chance (i.e., randomization). Patients in the standard care group may not have the same benefits as patients in the intervention group.

XV. Patient/Caregiver Payment for Participation in Research

The patient and the caregiver will be paid $10 for completion of baseline questionnaires, $10 for completion of Day 7 questionnaires, and $20 for completion of the Day 30 questionnaire. The total payment you may receive is $40. If the patient/caregiver does not finish the entire study, they will be paid at the time they decide to stop taking part in the study.