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| TITLE: Pilot Testing of a Culturally Sensitive End-of-Life Care Intervention for African American Advanced Cancer Patients and their Caregivers  Click here to enter text. | | | | | |
| PRINCIPLE INVESTIGATOR(S): | | Ramona Rhodes | |  | SITE(S) (if applicable): |
| UT Southwestern Medical Center  Parkland Health and Hospital System |
| COORDINATING SITE: | | UT Southwestern Medical Center | |  |
| STUDY PERIOD | | | |  |
| START: | | 2/17/2016 | |  |
| LAST SUBJECT CONTACT: | | 2/17/2017 | |  |
| OBJECTIVES: | | | | | |
| To test the feasibility, acceptability, and preliminary efficacy of an educational intervention that addresses advance care planning, palliative care, and hospice among hospitalized African American advanced cancer patients. | | | | | |
| PARTICIPANTS | | | | | |
|  | ENROLLMENT | | ELIGIBILITY CRITERIA | | |
| Patients: | 22 | | Click here to enter text. **Eligible**  **patients were those who (1) identified as non-Hispanic**  **black; (2) had been diagnosed with advanced (stage III or**  **IV) breast, lung, or colorectal cancer or had stage II disease**  **with significant comorbidities, making them appropriate for**  **palliative care; (3) were able to read, write, and speak English;**  **(4) were competent to give informed consent; (5) were not**  **receiving palliative care or hospice care at the time of the**  **study; and (6) were hospitalized at the time of recruitment.** | | |
| Informal Caregivers: | 0 | | Click here to enter text. | | |
| Health Care Providers: | 0 | | Click here to enter text. | | |
| METHODOLOGY: | | | | | |
| Participants completed an in-person baseline assessment that captured data on sociodemographics, religious affiliation, and symptoms and QOL via the McGill Quality of Life Questionnaire. We assessed patients’ intent to complete an advance directive/living will (AD/LW), complete a medical power of attorney (MPOA), discuss palliative care, and discuss hospice with their doctor or health-care team. Stage in intent to complete ACP components, to discuss palliative care, and to discuss hospice was based on the Transtheoretical Stages of  Change model. Our questionnaire consisted of items that related to the specific stage of behavior change for ACP (completion of an AD/LW or MPOA), discussion with providers about palliative care, and discussion with providers about hospice.  The intervention did not prove to be feasible in the hospital setting. We had too few caregiver participants to include in our analyses. Consequently, the published manuscript describes the cohort of patients that participated and some specific outcomes (as noted above). | | | | | |
| INTERVENTION (if applicable): Participants randomized to the intervention arm of the study watched a culturally-sensitive video titled, “Planning for the Care that you Want.” This video was developed by the researchers, and consisted of videotaped interviews of African American health care providers who had experience with hospice and palliative medicine, African American clergy, African American caregivers of patients, and an African American hospice patient. The interview segments addressed advance care planning, palliative care, and hospice. Each patient was assisted in watching the video segments by an African American lay health advisor who had received training in having end-of-life discussions (Respecting Choices). | | | | | |
| Click here to enter text. | | | | | |
| MEASURES: | | | | | |
| 1. Sociodemographics: Age, gender, primary cancer diagnosis, stage, religion, marital status, insurance status, total household income 2. Stage of Intent to: 1) complete an advance directive and/or medical power of attorney, 2) discuss palliative care with their health care team, 3) discuss hospice with their health care team, as measured by the Transtheoretical Stages of Change Model 3. Quality of Life (McGill QOL Questionnaire) 4. Completion of advance directive/MPOA, access of palliative care (inpatient or outpatient), hospice enrollment at study’s end (done by chart abstraction) | | | | | |

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| SUBJECT FLOW (CONSORT): NA |
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| BASELINE CHARACTERISTICS (TABLE 1)   |  |  | | --- | --- | | **Patient Characteristics at Baseline** | **All**  N = 22 | | **Age in Years, median (range)** | 59.5 (36 -78) | | **Gender**  Female  Male | 14 (63.6)  8 (36.4) | | **Primary Cancer Diagnosis**  Colon/Colorectal  Breast  Lung | 16 (33.3)  21 (43.8)  11 (22.9) | | **Cancer Stage**  1  2  3  4 | 0 (0)  4 (18.2)  5 (22.7)  13 (59.1) | | **Religion**  Protestant  Other  None  Baptist | 5 (22.7)  5 (22.7)  1 (4.6)  11 (50.0) | | **Marital Status**  Married  Divorced  Separated  Never Married  Widowed | 4 (18.2)  8 (36.4)  3 (13.6)  4 (18.2)  3 (13.6) | | **Medicare Part A**  Yes  No  Don’t know | 7 (31.8)  14 (63.6)  99 (4.6) | | **Medicaid**  Yes  No  Don’t Know | 7 (31.8)  14 (63.6)  1 (4.6) | | **County Financial Assistance**  Yes  No  Don’t Know | 14 (63.6)  7 (31.8)  1 (4.6) | | **Total Household Income**  $0 – 10,999  $11,000 - $20,999  $21,000 - $30,999  $31,000 - $50,999  $51,999 - $99,999  $100,00 or more  Don’t know | 8 (36.4)  3 (13.6)  3 (13.6)  2 (9.1)  1 (4.5)  1 (4.6)  4 (18.2) | | **ACP Outcomes at 12 Months** |  | | **Advance Directive/Living Will in Patient’s Chart** | 1 (5.0) | | **Medical Power of Attorney in Patient’s Chart** | 8 (36.4) | | **Out of Hospital Do Not Resuscitate Order in Patient’s Chart** | 2 (9.5) | | **Patient seen in Palliative Care Clinic** | 8 (36.4) | | **Patient referred to Hospice** | 6 (27.2) | | **Died** | 12 (57.1) | | **Location of Death if Known**  Home  Hospital  Nursing Home  Hospice | 2 (13.3)  10 (66.7)  0 (0)  0 (0) | | **Median Time to Death from Baseline Assessment, Days (Range)** | 79 (20 – 361) | |

**PCRC STANDARDIZED DATA ELEMENTS**

***Please see the separate information sheet*** [***“DISC Standardized Data Elements”***](file:///C:\Users\rrhode\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\XUS9EWQX\Info%20Sheet%20-%20DISC%20Standardized%20Data%20Elements_v2018.08.docx) ***for the exact wording and format of the data elements.***

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| **DATA ELEMENT** | **Collected?** | **Var Name(s)** | **Data source (e.g. self-report, EHR) or reason not applicable** |
| 1. **Site ID (if multi-site)** |  |  |  |
| 1. **Who is the research participant? (e.g., patient, caregiver, etc.)** |  | lah\_ptid, |  |
| 1. **Sex** |  | ppra\_gender | self-report |
| 1. **Ethnicity** |  | ppra\_ethnicity | self-report |
| 1. **Race** |  |  | All self-identify as African American |
| 1. **Age in years** |  |  | self-report, EHR |
| 1. **Current Marital Status** |  | ppra\_marital | self-report |
| 1. **Primary life-limiting diagnosis/illness** |  | med\_primcare | EHR |
| 1. **Performance status (AKPS)** |  |  |  |
| 1. **Enrolled in Hospice** |  | med\_hospice | EHR |
| * 1. **If yes to hospice, where is hospice care provided?** |  |  |  |
| 1. **Receiving Palliative Care (PC)?** |  | med\_pmh\_pcc | EHR |
| * 1. **If yes to receiving PC, where is PC provided?** |  | med\_pmh\_pcc or med\_ad\_pcc | EHR (clinic only) |
| 1. **Source of Death information** |  |  |  |
| 1. **Location of Death** |  | med\_dead\_loc | EHR |
| 1. **Enrolled in Hospice at time of death?** |  | Click here to enter text. |  |
| 1. **Receiving PC at time of death?** |  |  |  |

***Cells in blue only need to be collected for patient research participants. Cells in orange should be collected regardless of participant type.***

**PATIENT REPORTED OUTCOME INSTRUMENTS**

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| **CONTENT**  *(e.g., PS)* | **ABBREV**  *(e.g., AKPS)* | **INSTRUMENT NAME**  *(e.g., Australian Modified Karnofsky Performance Status)* |
| Quality of Life | N/A | McGill Quality of Life Questionnaire |
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