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| TITLE:  Testing PCforMe: a Web-Based Tool to Prepares Patients for Palliative Care. | | | | | |
| PRINCIPLE INVESTIGATOR(S): | | Arif Kamal MD, MBA, MHS | |  | SITE(S) (if applicable): |
| Click here to enter text. |
| COORDINATING SITE: | | Duke University | |  |
| STUDY PERIOD | | | |  |
| START: | | 1/11/17 | |  |
| LAST SUBJECT CONTACT: | | 2/26/18 | |  |
| OBJECTIVES: | | | | | |
| The primary objective of this study was to test the usability of PCforMe, a web-based preparation and engagement tool about palliative care, during a pre-visit pilot trial in outpatient palliative care at the Duke Cancer Institute Palliative Care Clinic. Secondary objectives were to measure change in palliative care knowledge, and impact on perceived efficacy for the patient-physician interaction to prepare effect sizes calculations for a future multi-center trial. | | | | | |
| PARTICIPANTS | | | | | |
|  | ENROLLMENT | | ELIGIBILITY CRITERIA | | |
| Patients: | 80 | | P**atients scheduled for a new (initial) Palliative Care Visit in the Duke Cancer Institute Palliative Care Clinic; age 22 y/o or older, with a serious illness as defined by the PC clinician; English-speaking; Able to provide consent and complete the research forms** | | |
| Informal Caregivers: | 0 | | N/A | | |
| Health Care Providers: | 0 | | N/A | | |
| METHODOLOGY: | | | | | |
| We conducted a pragmatic, sequential, randomized pilot trial to evaluate the usability of PCforMe as a tool to prepare subjects scheduled for an initial (new) outpatient palliative care consultation in the Duke Cancer Institute Palliative Care Clinic. Eighty patients who were scheduled for a new (initial) Palliative Care Visit in the Duke Cancer Institute Palliative Care Clinic were consented. We accrued up to 40 subjects into each of two arms. | | | | | |
| INTERVENTION (if applicable): | | | | | |
| We 1:1 randomized patients to an Active Control arm or Intervention arm. Both arms received a tablet computer (iPad or Galaxy Tab based on preference) connected to the internet with disposable headphones to use for up to 30 minutes. Subjects in the Active Control arm received a list of three nationally-recognized websites to receive information on palliative care – [www.palliativedoctors.org](http://www.palliativedoctors.org); getpalliativecare.org; and Wikipedia “Palliative Care” <https://en.wikipedia.org/wiki/Palliative_care>. Intervention Arm subjects will receive access to PCforMe. PCforMe is an online, web-based, interactive tool to prepare patients for a clinical palliative care encounter. PCforMe is accessible through [www.pcforme.org](http://www.pcforme.org), using password 6030. It does not collect any patient information, including identifiers (e.g. name, email address, disease, location) or health information (e.g. disease, symptom severity or location). The system uses a combination of animated videos and user-answered questions to generate a “Palliative Care Passport”, which is a summary of information entered into the system. Research staff will print out the Passport for patients and hand it to them prior to the appointment. Queries for users include standard-of-care questions asked by palliative care clinicians, including areas that patients want to more learn about. No diagnoses, medication advice, or clinical assessments are made or given. | | | | | |
| MEASURES: | | | | | |
| All consented participants completed assessments prior to the palliative care clinician visit. All completed the PEPPI, Change in Knowledge, and Single-item Prepared instrument prior to randomization along with a demographics screen   * Perceived Efficacy for the Patient-Physician Interaction (PEPPI) – 5-item, Likert scale instrument * Single item “Prepared” instrument – “I feel prepared for my palliative care appointment” (5-point Likert response – Strongly Disagree, Disagree, Neither Agree or Disagree, Agree, Strongly Agree) * Palliative Care Knowledge instrument – 5-item, multiple choice assessment of palliative care knowledge * Demographics Screen – 5-item assessment of patient demographics, including gender, race, ethnicity, marital status, and highest level of education   After randomization and use of either the Active Control resources or PCforMe, subjects completed:   * Perceived Efficacy for the Patient-Physician Interaction (PEPPI) – 5-item, Likert scale instrument * Single item “Prepared” instrument – “I feel prepared for my palliative care appointment” (5-point Likert response – Strongly Disagree, Disagree, Neither Agree or Disagree, Agree, Strongly Agree) * Palliative Care Knowledge instrument – 5-item, multiple choice assessment of palliative care knowledge * System Usability Scale – 10-item, 5-point Likert scale assessment of usability | | | | | |

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| SUBJECT FLOW (CONSORT): |
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| STUDY CALENDAR: |

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| BASELINE CHARACTERISTICS (TABLE 1) |

**PCRC STANDARDIZED DATA ELEMENTS**

***Please see the separate information sheet*** [***“DISC Standardized Data Elements”***](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.)** |  |  |  |
| 1. **Sex** |  |  |  |
| 1. **Ethnicity** |  |  |  |
| 1. **Race** |  |  |  |
| 1. **Age in years** |  |  |  |
| 1. **Current Marital Status** |  |  |  |
| 1. **Primary life-limiting diagnosis/illness** |  |  |  |
| 1. **Performance status (AKPS)** |  |  |  |
| 1. **Enrolled in Hospice** |  |  |  |
| * 1. **If yes to hospice, where is hospice care provided?** |  |  |  |
| 1. **Receiving Palliative Care (PC)?** |  |  |  |
| * 1. **If yes to receiving PC, where is PC provided?** |  |  |  |
| 1. **Source of Death information** |  |  |  |
| 1. **Location of Death** |  |  |  |
| 1. **Enrolled in Hospice at time of death?** |  |  |  |
| 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)* |
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