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| TITLE:  Telephone Implementation of Mindfulness-Based Multi-Symptom CBT for Advanced Cancer Patients | | | | | |
| PRINCIPLE INVESTIGATOR(S): | | Jennifer Plumb Vilardaga, PhD | |  | SITE(S) (if applicable): |
| Click here to enter text. |
| COORDINATING SITE: | | Duke University | |  |
| STUDY PERIOD | | | |  |
| START: | | June, 2017 | |  |
| LAST SUBJECT CONTACT: | | September 8, 2018 | |  |
| OBJECTIVES: | | | | | |
| Click here to enter text. | | | | | |
| PARTICIPANTS | | | | | |
|  | ENROLLMENT | | ELIGIBILITY CRITERIA | | |
| Patients: | 24 | | Age 21+, solid tumor cancer, stage IV or IIIc (lung). | | |
| Informal Caregivers: | 0 | | Click here to enter text. | | |
| Health Care Providers: | 0 | | Click here to enter text. | | |
| METHODOLOGY: | | | | | |
| Open trial, pre and post assessment. | | | | | |
| INTERVENTION (if applicable): | | | | | |
| Four session (each approximately 45 minutes) behavioral protocol teaching coping skills for managing pain and symptoms. | | | | | |
| MEASURES: | | | | | |
| - Brief Pain Inventory  - Pain Disability Index  - PROMIS Adult Fatigue Profile Short Form  - The Hospital Anxiety and Depression Scale  - Acceptance and Action Questionnaire-II  - Bulls-Eye Values Survey  - Client Satisfaction Questionnaire | | | | | |

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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.)** |  |  | All participants are patients, no differential variable collected. |
| 1. **Sex** |  |  | EHR |
| 1. **Ethnicity** |  |  | Self-report |
| 1. **Race** |  |  | **Self-report** |
| 1. **Age in years** |  |  | EHR |
| 1. **Current Marital Status** |  |  | **Self-report** |
| 1. **Primary life-limiting diagnosis/illness** |  |  | Self report and EHR review |
| 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)* |
| Pain severity | BPI | Brief Pain Inventory |
| Pain disability | PDI | Pain Disability Index |
| Fatigue | PFSF | PROMIS Adult Fatigue Profile Short Form |
| Distress | HADS | The Hospital Anxiety and Depression Scale |
| Mindfulness & acceptance | AAQII | Acceptance and Action Questionnaire-II |
| Valued living | BEVS | Bulls-Eye Values Survey |
| Client Satisfaction | CSQ | Client Satisfaction Questionnaire |
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