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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.)**
 |[x]    | All participants are patients, no differential variable collected. |
| 1. **Sex**
 |[x]    | EHR |
| 1. **Ethnicity**
 |[x]    | Self-report |
| 1. **Race**
 |[x]    | **Self-report** |
| 1. **Age in years**
 |[x]    | EHR |
| 1. **Current Marital Status**
 |[x]    | **Self-report** |
| 1. **Primary life-limiting diagnosis/illness**
 |[x]    | 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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