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| TITLE: Psychological Intervention for Caregivers of Patients with Malignant GIiomas | | | | | |
| PRINCIPLE INVESTIGATOR(S): | | Deborah A. Forst, MD | |  | SITE(S) (if applicable): |
| N/A |
| COORDINATING SITE: | | Massachusetts General Hospital | |  |
| STUDY PERIOD | | | |  |
| START: | | 2/12/19 | |  |
| LAST SUBJECT CONTACT: | | 3/30/20 | |  |
| OBJECTIVES: | | | | | |
| To refine a caregiver-directed intervention and study protocol based on acceptability feedback from an open pilot study with exit interviews. | | | | | |
| PARTICIPANTS | | | | | |
|  | ENROLLMENT | | ELIGIBILITY CRITERIA | | |
| Patients: | N/A | | N/A | | |
| Informal Caregivers: | 10 | | Age ≥ 18; Identified by a patient with a malignant glioma (WHO Grade III or IV glioma) as the patient’s primary caregiver; The patient is receiving care at the MGH Cancer Center; The patient was diagnosed with a malignant glioma within the past 6 months; Able to speak and read in English; Generalized Anxiety Disorder 7-item (GAD-7) score ≥5; Participants may or may not be pregnant. | | |
| Health Care Providers: | N/A | | N/A | | |
| METHODOLOGY: | | | | | |
| We conducted a pilot study of NeuroCARE, our psychological intervention for caregivers of patients with malignant gliomas. NeuroCARE involves six weekly or bi-weekly individual sessions with a study interventionist. We collected self-report data from caregiver participants both pre- and post-intervention, and we conducted qualitative exit interviews to gather feedback and assess intervention acceptability. Information about patient diagnoses was extracted from the medical record. Caregivers were identified by patients, clinicians, or study staff. | | | | | |
| INTERVENTION (if applicable): | | | | | |
| We utilized the findings from our longitudinal and qualitative studies and a thorough review of the literature to identify the necessary components of our caregiver intervention, NeuroCARE. The preliminary content includes three essential components: 1) a psychoeducational component to address preparedness, manage expectations, and develop caregiving skills; 2) a psychosocial component focusing on coping strategies, mindfulness, and facilitating acceptance while living with uncertainty; and 3) a self-care component to promote caregiver health and well-being. The psychological intervention consists of six individual sessions, 45-50 minutes each. We conducted sessions via phone or video conference using a HIPAA-compliant video platform provided by MGH TeleHealth to minimize participant burden and facilitate adherence. A social worker or psychologist in the MGH Cancer Center specifically trained on the intervention content delivered the intervention to a participant. The study team created the Intervention Manual for our Psychological Intervention for Caregivers of Patients with Malignant Gliomas, which was used as the basis for the intervention. | | | | | |
| MEASURES: | | | | | |
| At the time of consent, we used the 7-Item Generalized Anxiety Disorder questionnaire to screen for anxiety in caregiver participants. Eligible caregivers then completed a brief locator and demographic survey, which included variables such as age, gender, race, ethnicity, employment status, income, and relationship to patient. After consent, participants completed a Pre-intervention (baseline) Assessment, and after their final intervention session, participants completed that same survey, now titled Post-intervention Assessment. The Assessment included five measures: The Hospital Anxiety and Depression Scale, the Caregiver Oncology Quality of Life Questionnaire, the Caregiver Reaction Assessment, the Lewis Cancer Self-Efficacy Scale, and the Measure of Current Status scale. We are using these measures, respectively, to assess anxiety and depression symptoms, quality of life, caregiving burden, self-efficacy, and perceived coping skills pre- and post-intervention. | | | | | |

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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”*](file:///C:\Users\skl72\Downloads\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) |  |  | EHR |
| 1. Who is the research participant? (e.g., patient, caregiver, etc.) |  |  | Self-report |
| 1. Sex |  |  | Via self-report, we collected gender (‘man’, ‘woman’, or ‘other, specify: \_\_\_’) |
| 1. Ethnicity |  |  | Self-report |
| 1. Race |  |  | Self-report |
| 1. Age in years |  |  | Self-report |
| 1. Current Marital Status |  |  | Via self-report, we collected current marital status, but with different wording, choices are: ‘married or living with someone as if married’, ‘Non-cohabiting relationship’, ‘Single, never married’, ‘Divorced or separated’, ‘Loss of long-term partner/widowed’, ‘Other (please specify)’ |
| 1. Primary life-limiting diagnosis/illness |  |  | EHR |
| 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)* |
| Generalized anxiety | GAD-7 | 7-Item Generalized Anxiety Disorder |
| Anxiety and depression symptoms | HADS | Hospital Anxiety and Depression Scale |
| Quality of life | CarGOQoL | Caregiver Oncology Quality of Life Questionnaire |
| Caregiving burden | CRA | Caregiver Reaction Assessment |
| Self-efficacy | CASE | Lewis Cancer Self-Efficacy Scale |
| Perceived coping skills | MOCS | Measure of Current Status Scale |