|  |
| --- |
| TITLE:A collaborative palliative and oncology care intervention to improve symptoms and coping during treatment for head and neck cancer |
| PRINCIPLE INVESTIGATOR(S): | Jessica Bauman, MD |  | SITE(S) (if applicable): |
| Click here to enter text. |
| COORDINATING SITE: | Fox Chase Cancer Center |  |
| STUDY PERIOD |  |
| START: | 1/1/2019 |  |
| LAST SUBJECT CONTACT: | 1/31/2020 |  |
| OBJECTIVES: |
| 1. **To assess the feasibility and acceptability of a collaborative palliative and oncology care intervention for patients with HNC receiving CRT.**
2. **To explore patient coping strategies longitudinally in relation to symptom burden, QOL, mood, and health care utilization.**
 |
| PARTICIPANTS |
|  | ENROLLMENT | ELIGIBILITY CRITERIA |
| Patients: | 20 | 1. adult patients (≥18 years) with a diagnosis of HNC for which they are undergoing CRT
2. receiving all oncology care at Fox Chase Cancer Center (FCCC)
3. able to speak and read in English or with assistance from an interpreter
 |
| Informal Caregivers: | 0 | Click here to enter text. |
| Health Care Providers: | 0 | Click here to enter text. |
| METHODOLOGY: |
| This is a prospective study evaluating the feasibility and acceptability of an outpatient collaborative palliative and oncology care intervention integrated with standard chemoradiation in 20 patients with newly diagnosed HNC.  |
| INTERVENTION (if applicable): |
| All participants will receive standard oncology care during CRT in combination with the palliative care collaborative intervention. Participants will first meet with a palliative care collaborative team during the first week of CRT. The palliative care clinicians at FCCC include physicians (MD), nurse practitioners (NP), and registered nurses (RN). Each collaborative team will consist of the primary palliative care RN as well as an overseeing palliative care MD or NP. After the first visit, the participants will meet with the RN weekly, and the MD or NP will be available for urgent issues and prescriptions. The RN will also call the participant during weeks 8-11 after CRT is over during the recovery period. This is primarily an outpatient intervention, but if a patient gets hospitalized, the palliative care team will also follow participants during their admission. The intervention visits will focus on coping and the following symptoms prevalent during CRT: (1) pain and mucositis, (2) nausea, (3) constipation, (4) fatigue, (5) sleep disturbances, (6) xerostomia, (7) thick mucus, and (8) depression.  |
| MEASURES: |
| (1) Demographics: Participants will self-report their age, sex, race/ethnicity, marital status, work status, and education. Clinical, disease, and treatment characteristics (e.g. cancer site, stage, HPV-status, date of diagnosis, medical comorbidities, prior treatment) will be obtained by research staff from the electronic medical record. (2) Symptom burden: We will use the MD Anderson Symptom Inventory-Head and Neck (MDASI-HN) to measure symptom burden. This 28-item questionnaire, which contains 9 HNC specific items to assess common symptoms is well validated and widely used in HNC56.  (3) QOL. We will use the Functional Assessment of Cancer Therapy-Head and Neck (FACT-HN) to assess QOL. This is a validated 39-item scale that measures four dimensions of QOL (physical, functional, emotional, and social well-bring) with 12 head and neck-specific items57.  (4) Mood: We will use the Hospital Anxiety and Depression Scale (HADS) to assess symptoms of depression and anxiety. This 14-item measure has been used extensively in patients with cancer58. (5) Coping: We will administer the Brief COPE to assess patient coping strategies59. This 28-item measure assesses coping strategies that people use in response to stress such as active coping, positive reframing, and behavioral disengagement. This well-validated measure has been extensively used in various patient populations including HNC25 and with patients receiving a palliative care intervention15. (6) Acceptability: We will assess acceptability of the intervention by asking questions at 1-month post CRT 2 closed-ended items with Likert Scale ratings of 1-4 (i.e. whether they found the palliative care team helpful and whether they would recommend them to others) and 3 open-ended questions about their perceptions of the intervention).(7) Health care utilization: At the end of CRT, we will perform chart reviews to record ER visits, hospitalizations, feeding tube placement, weight changes, radiation treatment breaks, and chemotherapy dose intensity. We will also record medications prescribed and any referrals (i.e. social work, psychiatry). |

|  |
| --- |
| SUBJECT FLOW (CONSORT): |
|  |

|  |
| --- |
| STUDY CALENDAR: |

|  |
| --- |
| BASELINE CHARACTERISTICS (TABLE 1) |

**PCRC STANDARDIZED DATA ELEMENTS**

***Please see the separate information sheet*** [***“DISC Standardized Data Elements”***](file:///C%3A%5CUsers%5Cbaumanjr%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CTPOQ1LJD%5CInfo%20Sheet%20-%20DISC%20Standardized%20Data%20Elements_v2018.08.docx) ***for the exact wording and format of the data elements.***

|  |  |  |  |
| --- | --- | --- | --- |
| **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**

|  |  |  |
| --- | --- | --- |
| **CONTENT***(e.g., PS)* | **ABBREV***(e.g., AKPS)* | **INSTRUMENT NAME***(e.g., Australian Modified Karnofsky Performance Status)* |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |