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| TITLE:  The Impact of Age on Early Palliative Care for Patients with Advanced Lung and Non- Colorectal Gastrointestinal Malignancies | | | | | |
| PRINCIPLE INVESTIGATOR(S): | | Ryan Nipp | |  | SITE(S) (if applicable): |
| N/A |
| COORDINATING SITE: | | Massachusetts General Hospital | |  |
| STUDY PERIOD | | | |  |
| START: | | 7/1/16-6/30/17 | |  |
| LAST SUBJECT CONTACT: | | N/A | |  |
| OBJECTIVES: | | | | | |
| Aim: To determine if age moderates the effect of early PC on patients’ QOL, mood, prognostic awareness and coping. | | | | | |
| PARTICIPANTS | | | | | |
|  | ENROLLMENT | | ELIGIBILITY CRITERIA | | |
| Patients: | 350 | | In the parent trial, we enrolled 350 patients with newly diagnosed (within the previous eight weeks) incurable lung or non-colorectal gastrointestinal cancer presenting to Massachusetts General Hospital (MGH) from May 2011 to July 2015. Patients were also required to receive their care at MGH, be at least 18 years of age, have no history of therapy for metastatic disease, have an Eastern Cooperative Oncology Group performance status of 0 to 2, and be able to read and respond to questions in English or complete questionnaires with minimal assistance from an interpreter. We excluded patients already receiving palliative care services, those needing immediate referral for palliative care or hospice, and those with significant psychiatric or other comorbid disease prohibiting participation. | | |
| Informal Caregivers: | N/A | | N/A | | |
| Health Care Providers: | N/A | | N/A | | |
| METHODOLOGY: | | | | | |
| See full publication:  **Nipp RD, El-Jawahri A, Traeger L, Jacobs JM, Gallagher ER, Park ER, Jackson VA, Pirl WF, Temel JS, Greer JA. Differential effects of early palliative care based on the age and sex of patients with advanced cancer from a randomized controlled trial. Palliat Med. 2018 Apr;32(4):757-766. PMID: 29323617**  Briefly, we conducted a secondary, exploratory analysis of data collected from a randomized trial of early palliative care integrated with oncology care compared with usual oncology care. The study procedures have been previously described, but briefly, we randomly assigned patients in a 1:1 fashion with newly diagnosed, incurable lung or non-colorectal gastrointestinal malignancies to receive early palliative care integrated with oncology care or oncology care alone. Patients assigned to early palliative care met with a member of the outpatient palliative care team, which consisted of board-certified palliative care physicians and advanced-practice nurses, within four weeks after enrollment and at least monthly thereafter until death. Patients assigned to usual oncology care were not referred to palliative care unless requested by the patient, family, or oncologist. The Dana-Farber/Harvard Cancer Care institutional review board approved the study protocol. | | | | | |
| INTERVENTION (if applicable): | | | | | |
| N/A | | | | | |
| MEASURES: | | | | | |
| See full publication:  Nipp RD, El-Jawahri A, Traeger L, Jacobs JM, Gallagher ER, Park ER, Jackson VA, Pirl WF, Temel JS, Greer JA. Differential effects of early palliative care based on the age and sex of patients with advanced cancer from a randomized controlled trial. Palliat Med. 2018 Apr;32(4):757-766. PMID: 29323617  **We evaluated patients’ QOL using the Functional Assessment of Cancer Therapy-General (FACT-G), which has been validated for use in multiple care settings and with diverse tumor types.**  **We assessed patients’ mood symptoms using the Patient Health Questionnaire 9 (PHQ-9).**  **We used the Brief COPE to assess patients’ use of coping strategies.** | | | | | |

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| SUBJECT FLOW (CONSORT):  See publication of the parent trial:  Temel JS, Greer JA, El-Jawahri A, Pirl WF, Park ER, Jackson VA, Back AL, Kamdar M, Jacobsen J, Chittenden EH, Rinaldi SP, Gallagher ER, Eusebio JR, Li Z, Muzikansky A, Ryan DP. Effects of Early Integrated Palliative Care in Patients With Lung and GI Cancer: A Randomized Clinical Trial. J Clin Oncol. 2017 Mar 10;35(8):834-841. PMID: 28029308 |
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| STUDY CALENDAR:   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **PILOT GRANT TIMELINE** | | | | | | | | | | | | | | | | | | U24 Fiscal Year Timing |  |  | U24 Year 4 | | | | | | | | | | | |  |  | | Pilot Award Timing |  |  | Revised 1 Year: July 1, 2016 – June 30, 2017 | | | | | | | | | | | | Post | | |  |  | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | | **Activities** |  | *Pre* | *M1* | *M2* | *M3* | *M4* | *M5* | *M6* | *M7* | *M8* | *M9* | *M10* | *M11* | *M12* |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | Start Up: IRB / Database set up |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | Data Cleaning & Analysis |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | Writing |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | Publication |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | PCRC Final Report |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | XX | |

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| BASELINE CHARACTERISTICS (TABLE 1)  See full publication:  Nipp RD, El-Jawahri A, Traeger L, Jacobs JM, Gallagher ER, Park ER, Jackson VA, Pirl WF, Temel JS, Greer JA. Differential effects of early palliative care based on the age and sex of patients with advanced cancer from a randomized controlled trial. Palliat Med. 2018 Apr;32(4):757-766. PMID: 29323617 |

**PCRC STANDARDIZED DATA ELEMENTS**

***Please see the separate information sheet*** [***“DISC Standardized Data Elements”***](file:///C:\Users\rdn4\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\K6WRN5DW\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)** |  | N/A | N/A |
| 1. **Who is the research participant? (e.g., patient, caregiver, etc.)** |  | N/A | N/A |
| 1. **Sex** |  | Female\_sex | Chart review |
| 1. **Ethnicity** |  | ethnicity\_patient | Self-report |
| 1. **Race** |  | race\_patient | Self-report |
| 1. **Age in years** |  | age | Chart review |
| 1. **Current Marital Status** |  | pt\_marital\_status; relationship\_status\_patient; pt\_Married | Self-report |
| 1. **Primary life-limiting diagnosis/illness** |  | bin\_cancer\_type; CancerType\_Dich | Chart review |
| 1. **Performance status (AKPS)** |  | ps\_date\_enrolled | Chart review |
| 1. **Enrolled in Hospice** |  |  |  |
| * 1. **If yes to hospice, where is hospice care provided?** |  |  |  |
| 1. **Receiving Palliative Care (PC)?** |  | random | N/A |
| * 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)* |
| Quality of life | factg | Functional Assessment of Cancer Therapy: General (FACT-G) |
| Coping strategies | briefcope | The Brief COPE |
| Depression | phq | Patient Health Questionnaire-9 |
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