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Protocol and pilot testing: The feasibility and acceptability of a nurse-led telephone-based palliative care intervention for patients newly diagnosed with lung cancer

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1. Background

Palliative care improves symptom burden, cancer distress, patient and family satisfaction, and survival for patients with lung cancer [1–6]. Palliative care reduces cost or mitigates increased costs of aggressive end-of-life treatments that do not align with patients' goals [7–11]. Despite a growing body of evidence supporting the benefits for patients newly diagnosed with cancer, palliative care is not routinely offered until later in the disease trajectory [12,13].

Palliative care is traditionally delivered by interdisciplinary, subspecialty consultation teams [14]. The majority of palliative care services are provided during inpatient hospitalizations [14] with less availability of out- and home-based programs [8,15,16]. Recent endorsements by oncology and other professional societies to incorporate palliative care into routine care for patients with advanced cancers led to testing integrative care models [12,13,17,18]. However barriers, such as cultural differences between palliative and oncology medical sub-specialties [5,19], lack of consensus for performance measures [20,21], and limited practice capacity, contribute to the low adoption of integrated care models [22,23]. Similar to other specialty services, clinicians with expertise in palliative care are in short supply, potentially further limiting wider adoption of palliative care [24].

To potentially address gaps in workforce and care delivery, we designed a nurse-led, telephone-based palliative care intervention for patients with newly diagnosed lung cancer. We subsequently conducted a pilot study to assess feasibility and acceptability. We report the protocol, feasibility and participant acceptability of the pilot intervention. We also describe the changes implemented in the full scale efficacy trial.

2. Methods

2.1. Design

We conducted a pilot trial at the VA Puget Sound Health Care System. We a priori decided to recruit and randomize 40 outpatients newly diagnosed with lung cancer. Using this study design offered experience randomizing participants and developing and refining protocols to inform a full randomized clinical trial We allocated participants to either a combination of usual oncologic care with or without the palliative care intervention. All participants provided informed written consent. The VA Puget Sound Health Care Institutional Review Board (#00663) approved the protocol.

2.2. Participants

Study staff identified potential participants by reviewing weekly tumor board lists and new referrals to oncology and thoracic surgery services from March 2012 to December 2014. We sought to identify patients who had a new recent diagnosis of lung cancer (within the previous 8 weeks), were 40 years of age or older, were able to read and speak English and had telephone access. Patients were excluded from the study if they had cognitive impairment, could not participate in the informed consent process, or were enrolled in palliative or hospice care. For this pilot, we did not consider inclusion or exclusion based on cancer stage or histology. We based this decision on study results highlighting high symptom burden and the need for comprehensive symptom assessment and management for participants diagnosed with early stage lung cancer [3,25].

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2.3. Procedures

All participants completed baseline measures over the telephone with the guidance of a study coordinator. We abstracted from the medical record demographic information, lung cancer type and stage, lung cancer treatment, and spirometry. We asked participants to report co-morbidities and to identify the clinician primarily responsible for their lung cancer care. Participants assigned to the intervention group completed an exit survey assessing their acceptability of the intervention's structure, assessment of symptoms, treatment recommendations, and timeliness of follow-up by the nurse.

2.4. Nurse training

The study nurse completed the following educational activities to learn the principles of palliative care: 1. VA End-of-Life Nursing Education Consortium (ELNEC) course [26]; 2. a one day palliative care ethics course sponsored by the University of Washington; 3. independent readings from selected palliative care and lung cancer papers and state-of-the-science textbooks; 4. weekly patient reviews with palliative care clinicians; and 5. shadowing physicians, nurse practitioners and nurses in oncology, palliative care, pulmonary and thoracic surgery. To gain experience with discussing goals of care, the nurse applied principles used in communication interventions, for example Ask-Tell-Ask and “NURSE” a mnemonic summarizing how to respond and accept patients' emotions [27]. Initial training took approximately 80 h with 6 h/month of continuing informal education.

We trained a registered nurse with no prior oncology experience to deliver the intervention rather than a palliative care nurse or a nurse practitioner for several reasons. First, there are a limited number of nurses with specialty palliative care certification. Second, training registered nurses to deliver primary palliative care aligns with the Institute of Medicine's *Report on the Future of Nursing* [28] supporting nurses working at their highest scope of practice. Third, using a registered nurse supported our goal of keeping clinicians actively involved in their patients' care and treatment decisions as opposed to a nurse practitioner making independent treatment decisions.

2.5. Intervention

We developed an intervention based on the Chronic Care Model [29] incorporating symptom management, person-centered care plans, communication processes and utilization of supportive health care resources. The intervention consisted of 8 phone calls from the nurse over 3 months. The calls were scheduled weekly for 4 weeks, then every other week for 8 weeks. We based the call schedule on similar published interventions and from our clinical experience with patients usually experiencing greater symptoms and having more questions during the initial phase after diagnosis. All calls entailed delivering structured assessment of common symptoms including pain, dyspnea, fatigue, cough, anxiety, depression, and gastrointestinal (GI) complaints, along with implementing evidence-based non-pharmacological management protocols following Veteran Affairs (VA) endorsed End of Life Nursing Education Consortium (ELNEC) [26]. For each participant in the intervention arm, the study team developed a personalized care plan based on lung cancer stage, treatment and goals of care, and symptom assessements. This plan was updated and revised throughout the course of study. The intervention content topics include patient educational materials on lung cancer, goals of care discussions, and psychosocial needs assessments. See Supplement for intervention content, an example of a symptom assessment and management protocol and study communication processes.

2.6. Feasibility and acceptability measures

To assess feasibility, we measured the ability to enroll and retain participants and whether the nurse conducted the protocol-specified number of phone calls. We collected process measures including the time to train the nurse on the basic tenets of palliative care, the time to prepare, conduct and document participant calls, the number of recommendations the nurse made to clinicians, and clinician acceptance of recommendations. We measured clinician acceptance by the number of recommendations entered as orders in the medical record.

To assess acceptability of the intervention, we administered exit surveys to participants allocated to the intervention. Participants were asked to provide feedback on the number and length of phone calls, their experience describing symptoms over the telephone, if they received timely follow up on uncontrolled symptoms or problems and suggestions for improvements or topics that should be included to the intervention.

2.7. Data analysis

We estimated enrollment rate, retention and number of recommendations provided to each participant. We sought to follow an intent to treat approach. We examined characteristics of the participants. We used Wilcoxon rank sum statistic to compare age, treated as a continuous variable and Chi-squared or Fisher's exact test to test for differences in gender and ethnicity.

3. Results

3.1. Recruitment/enrollment

We invited 125 individuals to participate of whom 85 declined. Of the 41 individuals who completed the informed consent process, we randomized 40 participants of whom 36 completed the study (Fig. 1). Fifty-four individuals were not interested in participating in the study. The main reasons individuals declined were feeling overwhelmed with their cancer treatment or feeling the study would not benefit them. Sixteen individuals were unreachable, 7 became ineligible after initial screening, 4 were too ill and 4 did not disclose the reason for declining the invitation. Four participants were either lost to follow up (5%) or withdrew (5%) from the study due to enrolling in hospice or feeling too burdened by the cancer treatment.

3.2. Participant characteristics

We enrolled 40 participants who on average were white (95%),

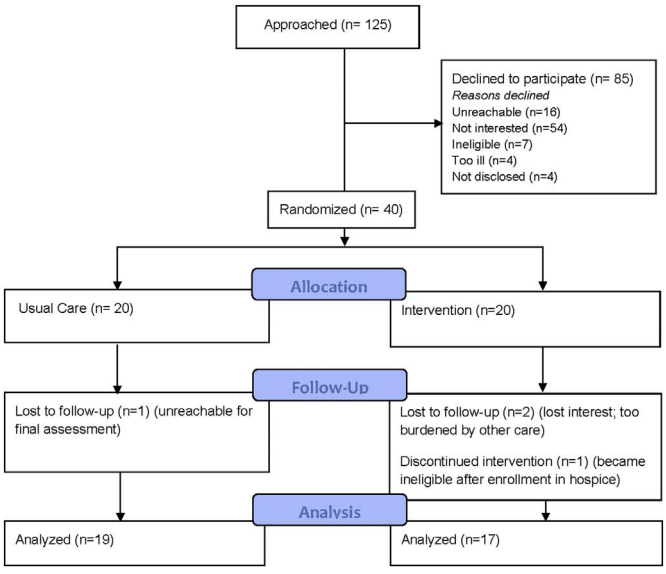

Fig. 1. Recruitment and Enrollment.