Document Coversheet

Study Title: Piloting 'mPal,' a Multilevel Implementation Strategy to Integrate Non-hospice Palliative Care Into Advanced Stage Lung Cancer Treatment

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	8/23/2023
NCT Number:	NCT05270395
IRB Number	74152
Coversheet created:	3/19/2025

Piloting 'mPal,' a Multilevel Implementation Strategy to Integrate Palliative Care into Advanced Stage Lung Cancer Treatment

Grant Title: Piloting 'mPal,' a Multilevel Implementation Strategy to Integrate non-hospice Palliative Care into Advanced Stage Lung Cancer Treatment

Grant Number: KL2TR001996

Funded by: National Institutes of Health, National Center for Advancing Translational Sciences

Protocol Number: 74152

National Clinical Trial (NCT) Identified Number: NCT05270395

Principal Investigator:

Laurie McLouth, Ph.D.
Assistant Professor
Behavioral Science
University of Kentucky College of Medicine
laurie.mclouth@uky.edu
Phone: 859-562-2526

Co-Investigator(s):

Susanne Arnold, MD
Professor
Internal Medicine
University of Kentucky College of Medicine
Associate Director of Clinical Translation, University of Kentucky Markey Cancer Center
Susanne.arnold@uky.edu

Ming-Yuan Chih, PhD
Health Sciences
University of Kentucky
m.chih@uky.edu

Jessica McFarlin, MD
Associate Professor of Neurology
University of Kentucky College of Medicine
Jessica.mcfarlin@uky.edu

Jerod Stapleton, PhD
Associate Professor of Health, Behavior & Society
University of Kentucky College of Public Health
Jerod.stapleton@uky.edu

Biostatistician:	Brent Shelton, PhD Professor Division Chief of Cancer Biostatistics University of Kentucky Markey Cancer Center bshelton@kcp.uky.edu Andrew Shearer SAS Programmer I Markey Cancer Center Core Support Ajsh225@uky.edu
Study Coordinators:	Vilma Bursac Senior Research Associate UK Center for Health Equity Transformation Vbu222@uky.edu Lexandra Overby Study Coordinator UK Center for Health Equity Transformation Lexandra.overby@uky.edu Kimberly Haney Research Program Manager UK Center for Health Equity Transformation kimberlyhaney@uky.edu
Project Support/Informatics:	Isaac Hands, MPH University of Kentucky College of Medicine isaac@kcr.uky.edu Chaney Kieckbusch University of Kentucky College of Medicine *Chaney.blu@uky.edu* Justin Levens University of Kentucky College of Medicine *Justin.levens@uky.edu*
Regulatory Contact:	Kimberly Haney Research Program Manager UK Center for Health Equity Transformation

kimberlyhaney@uky.edu

Version Number: 9

8/23/2023

Table of Contents

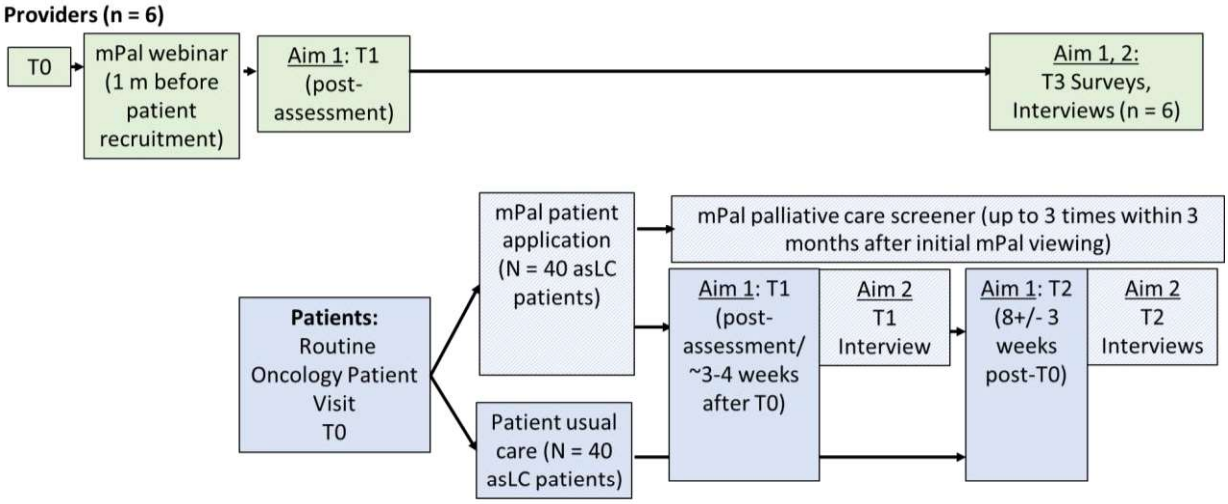
1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Piloting 'mPal,' a Multilevel Implementation Strategy to Integrate non-hospice Palliative Care into Advanced Stage Lung Cancer Treatment
Grant Number:	
Principal Investigator:	Laurie McLouth, PhD Assistant Professor, Behavioral Science
Study Description and Objectives:	This is a pilot RCT (40 patients mPal; 40 patients usual care; 6 providers not randomized) to test the feasibility and acceptability of a multilevel implementation strategy for outpatient palliative care (PC). Primary Objectives **1.** Evaluate mPal's feasibility and acceptability. We hypothesize we will be able to enroll ≥60% of asLC patients we approach (primary feasibility outcome),[1] retain ≥60% for one-month follow-up, and achieve mean patient and provider feasibility ratings of ≥ 3.5/5. For acceptability, we hypothesize we will be able to achieve mean patient and provider acceptability ratings of ≥ 3.5/5. We anticipate qualitative data (n = 40 mPal patient interviews; n = 6 provider interviews) will further support the ease of use and clinical value of mPal. 2. Obtain preliminary data on effectiveness and equity outcomes for a planned trial. In line with best practices for pilot studies,[2-4] we are not testing formal hypotheses for effectiveness outcomes; however, we will measure patient and provider PC knowledge[5,6] and motivation[7] and PC referrals, which we expect will improve with mPal. For equity outcomes, we will explore whether mPal appears similarly effective for patients with different characteristics (e.g., rural vs. urban, health literacy, income, race) by analyzing survey and semi-structured intervention data from mPal patients (n =40).
Endpoint:	Feasibility, primary endpoint defined as ≥60% eligible and approached patients enrolled
Study Population:	86 (n = 40, mPal; n = 40 usual care) patients with stage IIIb-IV non-small cell lung cancer or extensive stage small cell lung cancer, at least 3 weeks into treatment, ECOG 0-3, English speaking. (n = 6) oncology providers who provide care at least a half day/week to advanced stage lung cancer patients.
Stage:	Stage I (Pilot –Feasibility testing)

Facilities Enrolling:	UK Markey Cancer Center
Description of Study Intervention:	Multilevel implementation strategy to educate patients and providers about palliative care, identify patient palliative care needs, and facilitate referrals during treatment. mPal patient content includes 1) educational video, 2) assessment of PC knowledge, 3) assessment of PC needs, and 4) assessment of whether patients would like to meet with PC/discuss PC with their provider. mPal's provider content includes an educational presentation.
Study Duration:	3 months (patient participation)
Participant Duration:	Patients: ~2.5 hours over 6-10 weeks Providers: ~35-40 minutes over 12 weeks

1.2 SCHEMA



Note. T0 = baseline; T1 = assessment (~3-4 weeks after baseline); T2 = 8±3 week follow-up (after T0); T3 = ~3-month post-mpal implementation

2 INTRODUCTION

2.1 STUDY RATIONALE

Over 130,000 people are diagnosed with advanced stage lung cancer (asLC) in the U.S. each year. asLC patients experience significant psychological and physical sequellae from the disease and its treatment. Of the few supportive interventions tested in asLC patients, palliative care (PC) unequivocally has the strongest evidence base for addressing asLC patients' physical and psychological concerns. PC is an interdisciplinary approach to managing patients' physical, mental, and spiritual concerns. Multiple randomized controlled trials have shown delivering PC alongside cancer treatment improves asLC patient outcomes (e.g., symptom burden, quality of life) and reduces care costs. The evidence for PC is so strong that national clinical oncology guidelines now state PC should be delivered to all asLC patients within 12 weeks of starting cancer treatment. Despite these guidelines, less than 15% of asLC patients receive PC. Underutilization of PC is an implementation problem.

Barriers to implementing PC at multiple levels are well documented. Most asLC patients 1) do not know what PC is or what concerns it can address, 2) mistakenly equate PC with end of life, and 3) are reluctant to seek PC services without their cancer provider's recommendation. Cancer care providers 1) do not understand how PC can help manage patient concerns during cancer treatment, 2) do not have time to adequately assess and discuss concerns that PC could manage, and 3) fear patient reactions when mentioning PC. Finally, healthcare systems rely on providers to refer patients to PC, but do not provide the tools or training needed to support PC communication and referrals.

Our preliminary work has identified a multilevel implementation strategy as a promising approach to improve utilization of PC. We have developed our multilevel implementation strategy, called mPal, with patient, provider, and system administrator feedback. We now propose to conduct a pilot study of the mPal intervention with 60 patients (30 intervention, 30 control). Patients will be randomized to mPal's patient-level implementation strategies or usual care; provider and system intervention components will not be randomized.

2.2 BACKGROUND

A.1. Advanced stage lung cancer (asLC) is common, highly burdensome to patients, and disproportionately affects rural residents. Lung cancer has the second highest cancer incidence and highest cancer mortality in the U.S.[8] Each year, roughly 130,000 people are diagnosed with asLC. asLC is associated with high physical and psychosocial morbidities,[9] including poorer physical and role function,[10] higher depression,[11,12] and more unmet supportive care needs compared to other cancers.[13] asLC disproportionately affects rural, impoverished, medically underserved residents.[14] Kentucky leads the nation in asLC incidence and mortality.[15]

A.2. Palliative care (PC) is an evidence-based approach that mitigates patient burden, but it is underutilized. PC is an interdisciplinary approach to address the psychological, physical, and spiritual concerns of patients facing serious illness.[16] In asLC, delivering palliative care alongside cancer treatment has improved patient symptom burden, quality of life, mental health, as well as key care quality outcomes such as shared decision-making and appropriate end-of-life care.[17-23] The evidence behind PC is so strong that national guidelines and accrediting agencies now stipulate palliative care should be delivered to all asLC patients within 12 weeks of starting treatment.[17,24]

A.3. Overcoming barriers to PC implementation is a multilevel problem. Unfortunately, factors at the patient, provider, and healthcare system level lead to underutilization of PC (Fig. 1). Less than 15% of patients who could benefit from PC utilize it. Most patients have poor PC knowledge (i.e., do not know what palliative care is or what concerns it can address, equate PC with end of life, and/or fear using it means stopping cancer treatment),[25,26] will not seek PC without a provider recommending it,[27] and under-report PC concerns to their oncology team (see Preliminary Data).[27] Providers often also have poor PC knowledge (i.e., do not understand how PC can help manage patient concerns during treatment, equate it with end of life), are uncertain how to talk about PC with patients, and face time constraints during clinic visits to assess and address PC needs.[28-34] Most healthcare systems rely on providers to refer patients to PC, yet do not have systems in place to help identify appropriate patients and facilitate referrals.[31,35-47] Collectively, barriers to PC utilization fall into determinants of knowledge, motivation, and opportunity (Fig. 1).[48]

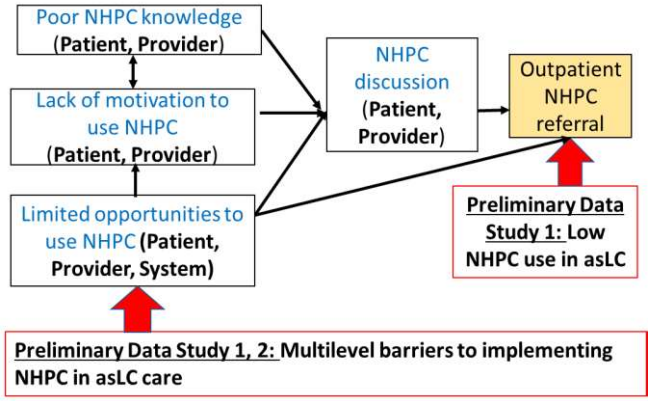


Figure 1. Conceptual Model of PC Implementation Problem

A.4. Existing interventions do not address multilevel determinants of PC. A multilevel strategy to address the problem of underutilization of PC has not been tested. Multilevel interventions target two or more levels of patients, providers, or healthcare systems. In cancer care, these have been successfully developed and applied to improve cancer screening. They have not been developed and applied to PC implementation. Instead, interventions targeting individual barriers to PC utilization have been developed and tested. [49-54] While showing some benefit, every intervention to date has significant shortcomings. Either they lack educational components to address knowledge barriers at the patient and provider levels, do not address provider motivation to use PC in clinical practice, or do not address system-level barriers to integrating PC. Critically, none have been designed for implementation in both community and academic cancer care settings—a major shortcoming given that most cancer care occurs in the community and that asLC disproportionately affects rural residents. A multilevel implementation strategy to address all key determinants of PC utilization is clearly needed.

3 OBJECTIVES

PRIMARY OBJECTIVES

1. **Evaluate mPal's feasibility and acceptability.** We hypothesize we will be able to enroll ≥60% of asLC patients we approach (primary feasibility outcome), retain ≥60% for one-month follow-up, and achieve mean patient and provider feasibility ratings of ≥ 3.5/5. For acceptability, we hypothesize we will be able to achieve mean patient and provider acceptability ratings of ≥ 3.5/5. We anticipate qualitative data (n = 30-40 mPal patient interviews; n = 6 provider interviews) will further support the ease of use and clinical value of mPal.

2. **Obtain preliminary data on effectiveness and equity outcomes for a planned trial.** In line with best practices for pilot studies, we are not testing formal hypotheses for effectiveness outcomes; however, we will measure patient and provider PC knowledge and motivation and PC referrals, which we expect will improve with mPal. For equity outcomes, we will explore whether mPal appears similarly effective for patients with different characteristics (e.g., rural vs. urban, health literacy, income, race) by analyzing survey and semi-structured intervention data from mPal patients (n =30-40).

4 STUDY DESIGN

4.1 OVERALL DESIGN

This is a Stage I, single-site trial to test the feasibility and acceptability of a novel intervention, mPal, through a pilot randomized controlled trial. Patient components are randomized. Provider components are not randomized. mPal is a multilevel implementation strategy designed to educate patients and providers about palliative care, identify patient palliative care needs, and facilitate referrals to palliative care during advanced stage lung cancer treatment.

To accomplish study objectives, we will conduct a pilot randomized controlled trial of the mPal protocol with 60 advanced stage lung cancer patients (40 mPal; 40 usual care); 6 oncology providers will be recruited and receive the provider components of mPal. The primary feasibility outcome that will be tested is patient enrollment (≥60%). We will also collect preliminary patient- and provider-reported data on effectiveness outcomes (e.g., PC knowledge), PC referrals (from the EHR), and will explore ways to improve effectiveness and equity outcomes (i.e., equitable reach of intervention) through semi-structured interviews with a purposive sample of mPal patients (n = 30-40) and providers (n = 6). See Study Schema for assessment timepoints.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

In line with best practices for pilot studies, we are testing feasibility, not formal hypotheses surrounding effectiveness outcomes. We are not randomizing provider and system-level strategies because 1) we do not plan to randomize providers in our next trial (rather, clinics will be randomized to start mPal at different times through a stepped-wedge design); and 2) intervention contamination would occur within the clinic.

4.3 JUSTIFICATION FOR INTERVENTION

mPal was developed based on theory, preliminary studies that identified key determinants of PC implementation in outpatient asLC care, and preliminary data to develop specific mPal content with patient and provider feedback.

4.4 END-OF-STUDY DEFINITION

A patient is considered to have completed the study if he or she has completed the baseline assessment and the follow-up (T2) assessment. A provider is considered to have completed the study if they complete the baseline assessment and the follow-up (T3) assessment. The end of the study is defined as completion of the follow-up (T2 for patients; T3 for providers) and completion of EHR extraction for follow-up outcomes..

5 STUDY POPULATION

5.1 PATIENT INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. new or recurrent AJCC stage IIIb-IV non-small cell lung cancer or extensive stage small cell lung cancer
2. 18 years of age or older
3. ECOG performance status 0-3/Karnofsky 40-100;
4. At least 3 weeks into active oncologic treatment
5. Receiving treatment at Markey Cancer Center

Rationale: We chose to recruit at least one month after starting treatment to allow patients time to begin treatment and experience treatment-related side effects.

5.2 PATIENT EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Unstable brain metastases (i.e., progressive neurological deficits, inadequately controlled seizures, or requiring escalating steroid doses);
2. Cognitive (i.e., dementia) or psychiatric condition (e.g., psychotic disorder) for which participating would be inappropriate
3. Receiving palliative care
4. Unable to speak and read English.

5.3 PROVIDER INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Oncologist
2. Advanced practice providers and nurses who work with enrolled oncologists
3. Provides care at least a half day a week to advanced stage lung cancer patients at Markey Cancer Center

Note: Fellows will be allowed to participate in this study.

5.4 PROVIDER EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Unable to speak and read English.

5.5 SCREEN FAILURES

Screen failures will be defined as patients who consent to participate in this study but are not subsequently assigned to the study intervention due to ineligibility or are assigned to intervention, but do not meet eligibility criteria and are withdrawn by investigators. Patients who do not meet the criteria for participation in this trial because of meeting one or more exclusion criteria that are likely to change over time may be rescreened. Examples include improvement in functional status and a progression of disease or disease recurrence for which a patient will begin treatment for advanced stage disease. Rescreened participants will be assigned the same participant number as for the initial screening.

5.6 STRATEGIES FOR RECRUITMENT AND RETENTION, PARTICIPANT COMPENSATION

Recruitment and Enrollment.
As in prior work, we will use two primary recruitment strategies: direct patient referral from oncologists and providers at the Markey Cancer Center and review of patient (per report of patients coming to clinic with diagnostic codes for advanced stage lung cancer) and provider

appointment schedules at the MCC. Additional eligibility checks may need to occur from within the UKHC medical record. Study personnel will identify upcoming oncology appointments of patients pre-screened for eligibility. Study personnel will then recruit patients in person at clinic appointments, by telephone, Zoom, or through MyChart® after confirming with the oncology team that it is okay to approach the patient.

We are requesting a waiver of HIPAA authorization for recruitment purposes. This waiver will allow us to review appointment schedules at the MCC to pre-screen potential patients for eligibility through the electronic health record. Patients will be pre-screened for documentation in their EHR for inclusion and exclusion criteria.

Inclusion of Women and Minorities. Men and women of all races and ethnicities who meet the above-described eligibility criteria are eligible to participate in this study. We expect approximately 42% of participants to be women. Translating this to our sample size estimate of 80, we plan to enroll at least 33 women. We expect to enroll racially and ethnically diverse patients in proportions that reflect our catchment area (87% White, 9% Black or African American, <2% Hispanic, <1% Asian, <1% Native American).

Retention. We will use previous retention strategies, including reminding patients of study visits, and offering sessions and assessments when they are in clinic for care.

Participant Compensation. Patients will receive a $20 gift card for completing the baseline assessment (T0), $10 for T1 survey, $10 for the T1 interview (mPal only), $30 for the 8-week follow-up (T2), and $10 for the T2 interview (mPal only). Providers will have the option to accept $20 gift cards for completing T0 (baseline), $10 for T1 (post mPal viewing), $20 for completing T3 (~3 months post-mPal implementation) surveys; and $30 for the interview.

6 STUDY INTERVENTION

6.1 STUDY INTERVENTION ADMINISTRATION

6.1.1 STUDY INTERVENTION DESCRIPTION

Theoretical Model and Implementation Strategies Underlying mPal. mPal is based in the application of the Capability, Opportunity, Motivation Model of Behavior (COM-B) and the Behavior Change Wheel.[55,56] The COM-B distills 14 theory-based constructs that explain behavior (e.g., knowledge, beliefs about capabilities, environmental resources) into three domains. Capability refers to a person's mental and physical ability to engage in a behavior (e.g., knowledge); motivation to the processes energizing and directing behavior; and opportunity to factors beyond a person that enable a behavior. The Behavior Change Wheel specifies intervention functions (e.g., education) that target the COM-B constructs. The COMB-B/BCW model has been used to develop interventions and study their implementation in healthcare.[57,58] mPal's multilevel implementation strategies were selected using the Expert Recommendations for Implementing Change list of strategies[59] and Preliminary Studies.

mPal Content and Procedures. See attachments for intervention content. Operational details of the mPal intervention appear in Table 1. mPal's patient content can be delivered either through MyChart via a "MyChart questionnaire" or a web-based tool (developed with Markey Cancer Center in UK IRB# 63922). The mPal patient content is comprised of two components: (1) a one-time educational video and knowledge check questions that seek to educate patients about palliative care; and (2) a palliative care needs screener (e.g., symptom concerns, psychological, spiritual) with questions about whether patients would like to meet with palliative care or discuss palliative care and their palliative care needs with their oncology provider. Procedures for viewing the mPal patient educational tool will vary based on whether a patient has MyChart. Patients with MyChart will be sent a research message requesting they complete mPal roughly two days before their next clinic appointment. They can complete this either in clinic on a tablet with study staff or from home. Patients who do not have a MyChart account will view Markey's web-based tool on a tablet with study staff in clinic or through a personal link provided via REDCap. Patients responses to the mPal palliative care needs screener and desire for palliative care will be entered in their electronic health record for their oncology provider to view. As part of the intervention, study staff will distribute the Markey Cancer Center palliative care FAQ document to participants that indicate yes to wanting more palliative care information on the mPal tool. The delivery methods for this document include email, mail, in-person distribution, or distribution through MyChart or EPIC as part of an after-visit summary.

After patients complete the initial palliative care screener, it will be re-administered to patients at future oncology treatment visits up to 3 times over the 3-months following receipt of the mPal educational component, though patients will have the option to request to continue to take the screener as part of their cancer care. The screener can be readministered via MyChart, in-person via tablet, or in-person through the Welcome™ function in EPIC® at visit check-ins. If patients request to re-review the mPal education, it will be provided to them.

mPal's provider content includes a web-based tool that provides education on: 1) Evidence for PC, clinical guidelines, and practice standards; 2) Education about common misconceptions of PC/provider reported barriers; 3) PC resources available in their clinic; 4) mPal's patient and provider-facing procedures/content; and 5) case examples showing the use of mPal in PC discussions during LC care.

Table 1. Detailed Description of mPal

Function	Forms tested	ERIC Implementation Strategies[59]	Operational Details
Education – to target PC knowledge; motivation to use PC	Patient: • Web-based tool Provider: • Web-based tool/recorded presentation	Patient: • Distribute educational materials • Prepare patients to be active participants in their care Provider:	Patient: This tool will include: 1) a brief video describing PC; 2) an assessment of potential concerns to be addressed through PC (e.g., pain, worry about illness); 3) options to request a referral to PC and to talk with their oncology team about their concerns and about PC. Timing: Delivered 3 weeks after starting LC treatment to allow symptoms/concerns to emerge; PC screener readministered at cancer treatment/oncologist appointments up to 3 times in the 3-months after receiving the education component. Provider: Oncology providers will view a 15-20-minute mPal tutorial (recorded presentation) online at the time of their choosing. Presentation will review: 1) Evidence for PC, clinical guidelines, and

		• Distribute educational materials	practice standards; 2) Education about common misconceptions of PC/provider reported barriers; 3) PC resources available in their clinic; 4) mPal's patient and provider-facing procedures/content; and 5) case examples showing the use of mPal in PC discussions during LC care. Timing: Delivered one month before the patient-level intervention starts.
Incentivization – to increase provider motivation to use PC	Provider: • Patient PC needs from web-based tool populate in EHR along with clinical guideline alert • Performance reports	Provider: • Facilitate relay of clinical data to providers • Remind providers • Audit and feedback	Providers- Once a patient completes mPal, the patient's PC needs will populate in the EHR. This information can be pulled directly into the clinical encounter note. Timing: PC alerts will occur whenever a patient uses the mPal web-based tool.
Environmental Restructuring – to increase opportunities to use PC	System: • Referral template • EHR tool to identify high need patients	System: • Facilitate relay of clinical data to providers • Make billing easier	System: To increase patient and provider opportunities to use PC, we will program: 1) an EHR/provider-facing alert for patients whose mPal web-based tool assessment indicates high need for PC (e.g., multiple PC concerns, poor performance status); 2) a structured PC referral template providers can use.
PC = palliative care; ERIC = Expert Recommendations for Implementing Change; EHR = electronic health record			

6.1.2 ADMINISTRATION AND/OR DOSING

As described in Table 1, the patient intervention will be delivered during a routine oncology visit or at home through MyChart. It is expected to take ~15-20 minutes. Provider intervention content will be delivered at an existing lung cancer meeting or online through REDCap. It is expected to take ~15-20 minutes. Patients will be considered to have received a full dose of the intervention if they watch the video and complete the PC needs assessment in the web-based mPal tool. Providers will be considered to have received a full dose of the intervention if they watch the recorded presentation or attend it live.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

Because the primary component of this intervention is a web-based multicomponent tool, interventionist training and fidelity monitoring procedures are minimal. Dr. McLouth (PI) and the study team will conduct an in-person training with review of procedures and role plays. Dr. McLouth or another study team member will observe the first 2-3 patient intervention sessions in clinic and additional sessions as needed. The study coordinator who meets patients in clinic to show them the mPal tool will attend weekly team meetings to receive supervision.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

This is a randomized controlled trial design (patient-level randomization). Study staff and patients will not be blinded to allocation; however, study staff and patients will not know allocation until after a patient has completed the baseline questionnaire. The statistician will generate the randomization table, which will be implemented through REDCap.

6.4 CONCOMITANT THERAPY

Patients will be able to receive concomitant treatment while on study. This may include counseling, complementary and alternative therapies, psychotropic medications, and rehabilitation. Indeed, one of the anticipated effects of the intervention is a facilitated referral to supportive services, including palliative care. We will track concomitant treatment use through review of electronic health record for services used during the study intervention period as well as by asking patients at follow-up whether they engaged services while completing the intervention.

7 STUDY CONTROL CONDITION

7.1 CONTROL CONDITION DESCRIPTION

Only the patient level component of mPal is randomized. Patients not randomized to the mPal patient implementation strategies will receive usual care.

8 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

8.1 DISCONTINUATION OF STUDY INTERVENTION

If a patient or provider discontinues the intervention, but not the study, remaining study procedures will be completed (e.g., post-assessment). Patients and providers who discontinue the intervention will be asked to indicate the reason why they are discontinuing (e.g., intervention burden,; see withdrawal form). If a participant's post-assessment is due to be completed within 2 weeks of discontinuing the intervention, the post will be administered at the time of discontinuation. If the post assessment is scheduled for more than 2 weeks from the date they discontinue the intervention, the post assessment will be administered at the originally scheduled assessment.

Patients may be discontinued from the intervention by the investigative team if the study team or treating physician has concerns about the patient's mental status or psychological wellbeing, at which point procedures for managing patient safety and evaluating adverse events will be followed. The study will document reasons for discontinuing a patient.

8.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue a participant from the study for the following reasons:

- Significant study intervention non-compliance
- Lost-to-follow up; unable to contact subject (see Section 8.3, Lost to Follow-Up)
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant (Note: Patients who become hospitalized will still have option to continue the study to complete assessments).
- The patient meets an exclusion criterion (either newly developed [e.g., change in mental status] or not previously recognized) that precludes further study participation.

The reason for participant discontinuation or withdrawal from the study will be recorded. Patients who sign the informed consent form but do not receive the study intervention may be replaced. Patients who sign the informed consent form and receive the study intervention and subsequently withdraw, or are discontinued from the study, will not be replaced.

8.3 LOST TO FOLLOW-UP

A patient will be considered lost to follow-up if he or she fails to return an assessment and study staff are unable to contact the participant after at least 3 attempts.

The following actions will be taken if a patient fails to return to the clinic for a required study visit:

- Staff will attempt to contact the participant, reschedule the missed intervention within 10 days, counsel the participant on the importance of maintaining the assigned visit schedule and determine if the participant wishes to and/or should continue in the study
- Before a participant is deemed lost to follow-up, the investigator or staff will make every effort to regain contact with the participant (where possible, 3 telephone calls and check-in at upcoming cancer care visit, and if necessary, a certified letter to the participant's last known mailing address). These contact attempts will be documented in the participant tracking log.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

9 STUDY ASSESSMENTS AND PROCEDURES

9.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Screening. We will build a master list form in REDCap linking patient names, MRNs, and study IDs. We will build a separate REDCap form for screening. The eligibility screening form will include patient screener ID, date screened, date must be enrolled by (21 day window), eligibility criteria (e.g., performance status, time on cancer treatment, age, etc.), whether the patient is being rescreened for eligibility, and, if rescreened, the last date of screening. If deemed potentially eligible, additional fields will appear in the eligibility database for tracking dates of upcoming appointments and contact with patients. Patients must be enrolled within 21 days of screening or else they will need to be rescreened.

Administration of Questionnaires. Patient-reported measures related to a future efficacy trial and of treatment processes were chosen based on their validity and sensitivity to change in cancer patients[60] and recommendation for clinical trials. These measures will be completed by patients pre-intervention (TP0), ~4 weeks after baseline (T1), and post-intervention (~8-weeks after T0; TP2) on paper, online (REDCap), or by phone. For patients who use MyChart®, a link to the REDCap survey will be provided through a study research message delivered in MyChart®. Patients will use a participation ID on their questionnaires. If more than 30 days pass between baseline and participant viewing the mPal tool, key sections (e.g., palliative care knowledge, palliative care use) of the baseline questionnaire will be re-administered prior to viewing mPal. See **Table 2** for a list of measures to be administered, psychometric properties, assessment schedule, and role in analysis plan. All patient-reported measures will be entered in REDCap in the REDCap project built for those patients who enroll.

Interviews. Patients assigned to mPal (n = 20-40) will complete two interviews. The interviews will last approximately 10-15 minutes and will query overall satisfaction with the intervention, perceived impact of mPal on clinical care, and reasons patients chose or chose not to talk with their doctor about their palliative care needs. The interviews will take place over the phone, Zoom, or in-person, according to patient preference. Interviews will be conducted by the study team and audiorecorded. After each interview, the interviewer will write up observations in the form of field notes, which will include information about the setting (e.g., details about room if in-person vs. on the phone), personal environment (e.g., respondent's attitude and openness), social environment (e.g., presence of caregiver or others in room), and summary of patient's responses. Recordings will be transcribed verbatim, the transcripts checked for accuracy and deidentified.

Table 2. Aim 1 and 2 Measures						
Construct	**Description**	**Data Sources**	**Level**			**Schedule**
			Pt	Pv	Sy	
Aim 1. Implementation Outcomes						
Feasibility	FIM[61]: 4 item implementation measure of intervention feasibility (α = .89); Individual interviews (pts, pvs)	Survey; interviews	X	X		mPal Patients: T1 Providers: T3
Acceptability	AIM[61]: 4 item implementation measure of intervention acceptability (α = .85) individual interviews (pts, pvs)	Survey; interviews	X	X		mPal Patients: T1 Providers: T3
Aim 2. Effectiveness and Equity Outcomes related to Planned Future Trial						
PC referral	Proportion of patients in each arm who receive a referral to PC within 1-month (survey) and 3-months (EHR) post-mPal intervention	EHR, Survey	X		X	Patients: T2 (survey); System: 3-months post intervention (EHR)
PC knowledge	HINTS PC[6]: 10 items; assesses self-reported PC knowledge and PC perceptions. PACKS	Survey	X	X		Patients: T0, T1 (mPal only), T2 Providers: T0, T1, T3
Motivation to use PC	PCAS-9[7]; 9 items; assesses emotional, cognitive, and behavioral components of motivation to use PC (α's = .70-.90)	Survey	X	X		Patients: T0, T1 (mPal only), T2 Providers: T0, T1, T3
Opportunities to use PC	5 items; perceived ability to access PC. Based on preliminary study and literature.[40,42,43]	Survey,	X	X		Patients: T0, T2 Providers: T0, T3
PC discussion	2 survey items; Interview questions to supplement (experiences discussing PC during clinical encounters, quality of discussion, how mPal was used)	Survey, depth interviews	X	X		Patients: T0, T2 Providers: T0, T3
Demographics	15 items; sociodemographics, health literacy[62] (pts), PC training (providers)	Survey	X	X		Patients: T0 Providers: T0
Equity	Characteristics of mPal patients who do/do not seek PC referral and do/do not show knowledge increase; Interview with those who do/do not use PC; barriers	Survey, interviews	X	X		mPal Patients: T2, 3m post intervention
Note. Pt = Patient; PV = provider; Sy = System; T = timepoint; T0 = baseline; T1 = post mPal app viewing or knowledge check (pt assessment); post webinar viewing (providers); T2 = 8-week follow-up (pt assessment); T3 = post-patient-level intervention period (for providers)						

Review of Existing Data in EHR. As part of the consent, all patients will be asked to consent to a HIPAA release for permission to collect the following protected health information for up to 12 months post-enrollment:

- age
- gender
- racial/ethnic data
- zip code
- mailing address, email, phone number (for participant payments)
- lung cancer diagnosis (includes histology and stage)
- date started lung cancer treatment
- type of treatments received
- medical record number

- ECOG/Karnofsky performance status
- referrals for palliative care, palliative care consultations completed, referrals to other supportive care services (e.g., Social Work), dates of referrals and consultations
- Documentation of advance care planning/advance directive
- mPal palliative care screener results (for repeated screenings)

This information will be collected by study staff and entered in REDCap or obtained through clinical informatics service.

10 STATISTICAL CONSIDERATIONS

10.1 STATISTICAL HYPOTHESES

Primary Endpoint: We hypothesize that at least 60% of eligible patients approached will enroll in the mPal intervention.

10.2 SAMPLE SIZE DETERMINATION

The sample size of 80 patients is based on the goal of estimating the probabilities and means for 2 feasibility outcome measures (enrollment ≥ 60% [primary],[1,63] retention ≥ 60%). We will use feasibility outcomes to inform a future trial. For structured interviews, we anticipate we will be able to identify key themes with 20 interviews.[64]

10.3 POPULATIONS FOR ANALYSES

The patient sample (n = 40 mPal; n = 40 usual care) will be used to analyze feasibility and acceptability data and describe pre-post changes in patient-reported outcomes. The provider sample (n = 6) will be used to demonstrate feasibility of measurement collection.

10.4 STATISTICAL ANALYSES

10.4.1 GENERAL APPROACH

We will use descriptive statistics (means, standard deviations, median, range) to examine the distribution of continuous variables. We will calculate 95% CIs for each of the feasibility measures to determine the range of estimates that are consistent with our data.

We will use one-sample negative binomial probabilities and tests of binomial proportions to compare to hypothesized values. We will summarize reasons for ineligibility and refusal and compare patients who drop out or do not adhere by demographic and clinical characteristics. Ordinal scaled variables such as feasibility and acceptability will be compared between groups

before and after baseline (as well as change from baseline) using the Wilcoxon Rank Sum statistic. Within group comparison of the pre versus post baseline measures will be evaluated using the Wilcoxon Signed Rank statistic.

We will use qualitative methods to analyze patient and provider feedback from the exit interviews and descriptive statistics to summarize participants' acceptability, feasibility, and appropriateness ratings of the intervention. The interviews will be transcribed verbatim and managed in ATLAS.ti or other qualitative software for analysis. The PI and study coordinator will code interviews by domains (e.g., perceived impact of mPal on clinical care, barriers, facilitators to using mPal, suggested changes to improve equity of mPal). Data will be analyzed using thematic content analysis[65] to describe perceptions.

Statistical significance will be indicated by $p < .05$.

10.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

The primary outcome of the feasibility is enrollment (≥60%). A one-sample binomial test will be used to compare the observed enrollment percentage to 60%.

Enrollment (primary): Number of patients enrolled divided by the number of eligible patients approached

Retention: The percentage of patients and providers who complete baseline and follow-up questionnaires.

Acceptability: Mean post-treatment patient and provider ratings ≥ 3.5/5 on intervention acceptability, feasibility, and appropriateness (psychometrically validated measure; Table 2), and a brief semi-structured interview to explore factors associated with acceptability.

10.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

We will describe pre-post changes in the patient-reported outcome variables related to a future trial using univariate and bivariate statistics. Our chief goals will be to estimate the standard deviations of our key variables for use in planning future studies. We will examine, through the use of t-tests, whether pre-post changes in the mPal differ significantly from pre-post changes in the control group. If our intervention is successful, we would expect to see significantly greater improvement over time in our effectiveness outcomes (PC knowledge, motivation) in treatment vs. control. We will also examine correlations between changes in these measures and PC referrals; we expect changes in PC knowledge and motivation variables will be positively correlated with changes in PC referrals within both treatment and control groups.

11 RISK/BENEFIT ASSESSMENT

11.1.1 KNOWN POTENTIAL RISKS

The proposed study poses minimal risks. Potential risks that might exist fall into three categories: (a) risks associated with the intervention; (b) risks associated with research assessments, and (c) risks associated with potential loss of confidentiality. We describe each below.

Risks of the intervention. The intervention has no known risks. However, it is possible that for people who have misperceptions about palliative care (e.g., that it is only for people for whom cancer treatment is not working), there may be an initial negative reaction to being presented information about palliative care. It is also possible that some people may experience some mild distress when completing the palliative care needs assessment, which asks about common lung cancer symptoms and concerns (e.g., worry about family members). Both risks are expected to be rare occurrences and mild in severity.

Risks associated with research assessments. The instruments and methodologies are well tested and are not known to cause problems or distress on the part of the participants; however, there is the possibility that some individuals may find answering the questions distressing (e.g., asking about their palliative care knowledge) or boring. This risk is expected to be a rare occurrence and mild in severity.

Risks associated with potential loss of confidentiality and privacy. There is a risk of loss of confidentiality and privacy as patients may be met in person at Markey Cancer Center or receive phone/Zoom calls, emails, or MyChart® messages from the study coordinator. In addition, patients will complete research assessments using an online form in REDCap, which could possibly result in a loss of confidentiality. However, the research team will take every precaution to safeguard participant data.

11.1.2 KNOWN POTENTIAL BENEFITS

This study will determine whether it may be feasible to conduct a fully powered randomized controlled trial of mPal. It is also possible that patients who receive the mPal intervention may benefit from receiving education about an evidence-based intervention in cancer care (palliative care) which may impact their care and improve health outcomes. These benefits may or may not occur for any and all participants. Participants may experience some benefit from feeling that they have contributed to a study that can help inform ways to help future lung cancer patients. For society as a whole, the findings will inform future intervention development and testing with lung cancer patients. Future patients may benefit from an intervention that is low burden in terms of time and cost, potentially widely available due to delivery mode, and aligned with personal values and unmet supportive care needs.

11.1.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS AND PROCEDURES TO MINIMIZE RISKS

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. This study will determine whether the mPal tool is feasible for advanced stage lung cancer patients in primary oncology. Results of this study will inform whether an efficacy study is warranted.

Procedures to Minimize Risks.

Protection for risks associated with the intervention. The biggest risk we perceive with the intervention is distress resulting from the education about palliative care for patients in the intervention. This risk is reduced by the assessment that is built into the mPal tool, which asks patients to select what they learned about palliative care (e.g., that it is not the same as hospice, that it can be delivered at any time or stage of disease).

Protection for risks associated with assessment. Patients will give voluntary responses to questions; they are told that they can decline to answer any questions that they choose. If patients express distress or frustration with the questions, study staff will remind them that these questions are voluntary and that they are meant to apply to a broad range of patients and may not necessarily reflect each person's experience. If patients remain distressed, the study PI, Dr. McLouth or other qualified member of the study team will contact them. If concerns remain, participants will be directed either to the chair of the IRB to discuss their concerns about the assessments and will be referred for psychological services at the Markey Cancer Center.

Protection for risks associated with potential loss of confidentiality. Prior to any contact with study participants or data, the Principal Investigator will ensure study team members have completed required institutional training in maintaining confidentiality of study data. Further, all study staff will complete training in Good Clinical Practice, which is required for clinical trial research.

Assessments completed on paper will have the participant's assigned unique ID and not the participant's name on it. Assessments completed online will be done through a secure survey site, REDCap. REDCap requires HTTPS login access. Hypertext Transfer Protocol Secure (HTTPS) is a combination of the Hypertext Transfer Protocol with the SSL/TLS protocol to provide encryption and secure identification of the server. HTTPS connections are used for payment transactions on the Internet and for sensitive transactions in corporate information systems. Assessments completed on the phone with the study coordinator will be conducted an agreed upon time by the participant when they believe they will not be interrupted. The study coordinator will complete the phone assessments from a private office. At the start of the call, the study coordinator will query whether it is a good time and whether the participant is comfortable answering questions in their current location.

Data for all participants will be kept strictly confidential, except as mandated by law. All electronic data will be kept on UK OneDrive or REDCap. Any paper documentation will be kept in locked file cabinets or a locked file room. Participants will be assigned a numerical code for identification in the files. Names and other identifiers will be kept in separate password protected files. Audio data will be stored on UK's OneDrive.
All data presentation will be of aggregate-level data; patients will not be individually named.

Psychiatric emergencies. In the case of psychiatric emergencies, patient care will take precedence over treatment protocol. If the study coordinator or interventionist identifies concerns about a patient's mental state, the study PI or other qualified member of the study team will contact the participant and determine whether a referral to psychological counseling is needed or whether emergency services are needed. If the patient is able to continue the study, the PI or other qualified member of the study team will develop a follow-up plan using clinical judgment based upon the data and any additional information acquired through interview. Referrals and assistance will be given in obtaining appropriate treatment for any participant terminated from the study for safety issues. Reports will be filed with all necessary governing bodies, including the University of Kentucky IRB.

11.2 SAFETY MONITORING AND ADVERSE EVENTS

11.2.1 DEFINITION OF ADVERSE EVENTS

This study is considered to carry a low risk to patients. AEs will be reported if they are study related. For example, patient hospitalization or death due to disease is expected in this population and unlikely to be an AE related to the study. However, if the AE could be related the study (i.e., there is a temporal relationship between the study procedures and the event or reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE), it will be reported as an AE. An example of an AE for this study would be severe distress during the intervention session that requires additional clinical management for safety. Any psychiatric condition that is present at the time the patient is screened and enrolled will be considered as baseline and not reported as an AE. However, if the patient's condition deteriorates during the study, it will be reported as an AE.

The PI and/or other qualified Co-I will be responsible for reviewing the AE to grade its severity (mild, moderate, severe) and relatedness (definitely, probably, potentially) to the study intervention.

11.2.2 MONITORING FOR AE'S AND FOLLOW-UP

Several mechanisms for monitoring the occurrence of adverse events will be employed. The study coordinator will oversee day-to-day monitoring of the study activities and will have daily contact with the PI.

There will be ongoing communication among the research team. This will be facilitated by: 1) regular (weekly or bi-weekly) meetings with project staff and investigators to discuss study progress, reactions to the intervention, and any adverse events; 2) supervision of the study coordinator, and data manager. For medical adverse events, patients will contact their oncology care team or emergency medical services as they would in routine care.

11.2.3 ADVERSE EVENT REPORTING

The PI or designated personnel will be responsible for reporting the results of an AE evaluation to the NIH and the IRB as soon as possible, but no later than 14 working days after the study team first learns of the event.

11.3 UNANTICIPATED PROBLEMS

11.3.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

An example of an unanticipated problem would include loss of data or sensitive information due to a study laptop being stolen or a complaint from a participant or participant family member. If a participant complaint identifies a newly recognized risk, the informed consent document will be updated and previously enrolled participants will be informed of the additional potential risk.

11.3.2 UNANTICIPATED PROBLEMS REPORTING

The PI or designated personnel will report unanticipated problems to the IRB. This information will include a detailed description of the event, an explanation of the basis for determining that the event constitutes an unanticipated problem, and a description of any changes to the protocol or other corrective actions that have been take or are proposed in response to the unanticipated problem.

12 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

12.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

12.1.1 INFORMED CONSENT PROCESS

12.1.1.1 CONSENT

For patients, written documentation of informed consent will be required prior to completing the baseline assessment and randomization. The consent form will describe the intervention, randomization, study procedures, including audiorecording of the semi-structured interviews, risks, and potential benefits.

For providers, a study cover letter will be required prior to baseline assessment. The cover letter will describe the intervention, study procedures, including audiorecording of the semi-structured interview, risks, and potential benefits.

12.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Patients will provide written informed consent through a combined consent/HIPAA release form. The consent will describe the study purpose, procedures, risks, benefits, and provide PI contact information. The consent form will describe randomization and the two potential conditions (mPal intervention or usual care). It will also describe the possibility of being asked to complete an interview and the procedures for recording the interviews. Patients will be consented in person or remotely via REDCap or paper copies through mail. When consenting patients in person, we will ensure we are meeting in a private space with the patient (e.g., physician exam room, consult room, infusion room). When consenting patients remotely, we will first ensure the patient is in a place where they have privacy and feel comfortable having a conversation. We will then review the consent form over the phone or Zoom. The consent form will be reviewed with study personnel and patients will have opportunity to ask questions. To check understanding, patients will be asked to describe their understanding of key aspects of the study (rationale, what is involved, decision not to participate not affecting their medical care) and study staff will review any aspects that do not appear to be understood. As part of the consent, all patients will be asked to consent to a HIPAA release for permission to use the following protected health information, as well as the information collected for eligibility screening:
age
gender
racial/ethnic data
zip code
lung cancer diagnosis (includes histology and stage)
date started lung cancer treatment
type of treatments received
medical record number
ECOG/Karnofsky performance status

Palliative care screener results
referrals for palliative care, palliative care consultations completed, referrals to other supportive care services (e.g., Social Work), dates of referrals and consultations
advance care planning/advance directive

A copy of the consent form will be sent with the patient on paper or electronically and retained via paper or electronically for study records.

For oncology providers, we will provide a study information sheet (cover letter). The study information sheet will be provided online (REDCap), paper, over the phone, or emailed (see protocol 55171 for precedent). If reviewed over the phone, the study team will email the participant a copy of the study information sheet and review key information verbally. Providers will have opportunity to ask questions about the study. Completion of the survey and interview will indicate implied consent. Surveys and interviews pose no more than minimal risk to the provider and involve no procedures for which consent would normally be required outside a research setting. Study information (purpose, study requirements, risks/benefits, who to contact for questions, contact information for investigators) will be provided and potential participants will be invited to contact investigators with any questions regarding the study. Potential participants can refuse to participate in this study.

12.1.2 CONFIDENTIALITY AND PRIVACY

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection forms. All interactions with patients will be conducted in as private atmosphere as possible. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from patient data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed 6 years after the closure of the study, producing an anonymous analytical dataset. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

12.1.3 QUALITY ASSURANCE AND QUALITY CONTROL

Quality control procedures will be implemented as follows:

Informed consent. Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. This review will evaluate compliance with Good Clinical Practice, accuracy, and completeness. Feedback will be provided to the study team to ensure proper consenting procedures are followed.

Source documents and the electronic data. Some data will be initially captured on source documents (see **Section 12.1.4, Data Handling and Record Keeping**), but all will ultimately be entered into the study database.

The study team will download the REDCap data after the first 5 patients have enrolled to check for errors. We will perform logic and range checks. Patient-reported data and medical record data entered by the study coordinator in REDCap will be examined for accuracy. Specifically, the study team will compare the patient-reported packet with entries in REDCap for 50% of the data. The study team will review medical record data extracted for accuracy and consult with Dr. Arnold or other member of the thoracic oncology team on the protocol if there are questions about clinical data.

Intervention Fidelity. Consistent delivery of the study intervention will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in **Section 6.2.1, Interventionist Training and Tracking**.

Protocol Deviations. Protocol compliance will be monitored and discussed at weekly team meetings. The study team will review protocol deviations and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

12.1.4 DATA HANDLING AND RECORD KEEPING

12.1.4.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data sources include:

• information from the electronic medical record (e.g., patient eligibility screening and upon enrollment demographic, clinical, referral data; electronic only)

• audio recorded exit interviews and transcripts (electronic; patients and providers)

• surveys (electronic or paper; patients and providers)

• participant tracking (e.g., upcoming appointments; withdrawal; discontinuation; electronic)

• refusal and withdrawal forms (electronic; patients and providers)

• preferred contact information for payment (electronic or paper; patients and providers)

• study administration/tracking logs (electronic; study staff completes; e.g., payment logs, final study statues)

All data except for audiofiles and transcripts will be stored in REDCap, a secure electronic data capture system, or Excel behind a UK firewall on a study-specific shared drive. REDCap provides a real-time record of any changes made to data.

Patient-reported outcome data will be collected via mail, telephone, or in-person. Based on our prior studies, we anticipate that most patients will complete the assessments in-person with the study coordinator when they are at the Markey Cancer Center for other oncologic appointments.

12.1.4.2 STUDY RECORDS RETENTION

All records pertaining to the study will be retained for 6 years.

12.1.5 PROTOCOL DEVIATIONS

A protocol deviation is defined as any noncompliance with the clinical trial protocol. Deviations will be reported to the IRB and corrective actions will be developed by the study team and implemented.

12.1.6 PUBLICATION AND DATA SHARING POLICY

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals.

12.2 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
NSCLC	Non-small cell lung cancer
HIPAA	Health Insurance Portability and Accountability Act
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance

QC	Quality Control
SOA	Schedule of Activities
SOP	Standard Operating Procedure
UP	Unanticipated Problem

13 REFERENCES

1. Nipp RD, Temel B, Fuh CX, et al. Pilot Randomized Trial of a Transdisciplinary Geriatric and Palliative Care Intervention for Older Adults With Cancer. *J Natl Compr Canc Netw.* 2020;18(5):591-598.

2. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *Journal of Evaluation in Clinical Practice.* 2004;10(2):307-312.

3. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. *BMC Medical Research Methodology.* 2010;10(1):1.

4. Whitehead AL, Sully BGO, Campbell MJ. Pilot and feasibility studies: Is there a difference from each other and from a randomised controlled trial? *Contemporary Clinical Trials.* 2014;38(1):130-133.

5. Taber JM, Ellis EM, Reblin M, Ellington L, Ferrer RA. Knowledge of and beliefs about palliative care in a nationally-representative US sample. *PloS one.* 2019;14(8):e0219074.

6. Huo J, Hong Y-R, Grewal R, et al. Knowledge of Palliative Care Among American Adults: 2018 Health Information National Trends Survey. *Journal of Pain and Symptom Management.* 2019;58(1):39-47.e33.

7. Perry LM, Hoerger M, Malhotra S, Gerhart JI, Mohile S, Duberstein PR. Development and Validation of the Palliative Care Attitudes Scale (PCAS-9): A Measure of Patient Attitudes Toward Palliative Care. *Journal of Pain and Symptom Management.* 2020;59(2):293-301.e298.

8. Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer statistics, 2021. *CA: a cancer journal for clinicians.* 2021;71(1):7-33.

9. Vijayvergia N, Shah PC, Denlinger CS. Survivorship in Non-Small Cell Lung Cancer: Challenges Faced and Steps Forward. *Journal of the National Comprehensive Cancer Network : JNCCN.* 2015;13(9):1151-1161.

10. Reeve BB, Potosky AL, Smith AW, et al. Impact of cancer on health-related quality of life of older Americans. *J Natl Cancer Inst.* 2009;101(12):860-868.

11. Andrykowski MA, Steffens RF, Bush HM, Tucker TC. Disparities in mental health outcomes among lung cancer survivors associated with ruralness of residence. *Psycho-Oncology.* 2014;23(4):428-436.

12. Zabora J, BrintzenhofeSzoc K, Curbow B, Hooker C, Piantadosi S. The prevalence of psychological distress by cancer site. *Psycho-Oncology.* 2001;10(1):19-28.

13. Li J, Girgis A. Supportive care needs: are patients with lung cancer a neglected population? *Psychooncology.* 2006;15(6):509-516.

14. Zahnd WE, James AS, Jenkins WD, et al. Rural–urban differences in cancer incidence and trends in the United States. In: AACR; 2018.

15. Brainson CF, Huang B, Chen Q, et al. Description of a Lung Cancer Hotspot: Disparities in Lung Cancer Histology, Incidence, and Survival in Kentucky and Appalachian Kentucky. *Clinical Lung Cancer.* 2021.

16. Nurse NCPfQPCJTK. Clinical practice guidelines for quality palliative care. 2004;79(9):16.

17. Ferrell BR, Temel JS, Temin S, et al. Integration of Palliative Care Into Standard Oncology Care: American Society of Clinical Oncology Clinical Practice Guideline Update. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology.* 2017;35(1):96-112.

18. Bakitas MA, El-Jawahri A, Farquhar M, et al. The TEAM approach to improving oncology outcomes by incorporating palliative care in practice. 2017;13(9):557-566.

19. Smith CB, Phillips T, Smith TJ. Using the New ASCO Clinical Practice Guideline for Palliative Care Concurrent With Oncology Care Using the TEAM Approach. 2017(37):714-723.

20. Bakitas M, Lyons KD, Hegel MT, et al. Effects of a palliative care intervention on clinical outcomes in patients with advanced cancer: the Project ENABLE II randomized controlled trial. *JAMA.* 2009;302(7):741-749.

21. Bagcivan G, Dionne-Odom JN, Frost J, et al. What happens during early outpatient palliative care consultations for persons with newly diagnosed advanced cancer? A qualitative analysis of provider documentation. *Palliative medicine.* 2018;32(1):59-68.

22. Kavalieratos D, Corbelli J, Zhang D, et al. Association between palliative care and patient and caregiver outcomes: a systematic review and meta-analysis. *JAMA.* 2016;316(20):2104-2114.

23. Temel JS, Greer JA, Muzikansky A, et al. Early palliative care for patients with metastatic non–small-cell lung cancer. *New England Journal of Medicine.* 2010;363(8):733-742.

24. Surgeons ACo. Cancer Program Standards: Ensuring Patient-Centered Care. In. *Clinicial Services 2.4 Palliative Care Services*. Chicago, IL: American College of Surgeons 2016.

25. Taber JM, Ellis EM, Reblin M, Ellington L, Ferrer RA. Knowledge of and beliefs about palliative care in a nationally-representative U.S. sample. *PLOS ONE.* 2019;14(8):e0219074.

26. Zhu Y, Enguídanos S. When Patients Say They Know About Palliative Care, How Much Do They Really Understand? *Journal of pain and symptom management.* 2019;58(3):460-464.

27. Steffen L, Lycan T, Levine BJ, et al. Prognostic understanding and barriers to palliative care in patients with metastatic lung cancer on immunotherapy. In: American Society of Clinical Oncology; 2018.

28. Understanding the Barriers to Introducing Early Palliative Care for Patients with Advanced Cancer: A Qualitative Study. 2019;22(5):508-516.

29. Ahmed N, Bestall J, Ahmedzai SH, Payne S, Clark D, Noble B. Systematic review of the problems and issues of accessing specialist palliative care by patients, carers and health and social care professionals. *Palliative medicine.* 2004;18(6):525-542.

30. Buckley de Meritens A, Margolis B, Blinderman C, et al. Practice patterns, attitudes, and barriers to palliative care consultation by gynecologic oncologists. 2017;13(9):e703-e711.

31. Earp MA, Sinnarajah A, Kerba M, et al. Opportunity is the greatest barrier to providing palliative care to advanced colorectal cancer patients: a survey of oncology clinicians. *Current oncology (Toronto, Ont).* 2018;25(5):e480-e485.

32. Lynch S. Hospice and palliative care access issues in rural areas. *The American journal of hospice & palliative care.* 2013;30(2):172-177.

33. Schulman-Green D, Lin JJ, Smith CB, Feder S, Bickell NA. Facilitators and Barriers to Oncologists' Conduct of Goals of Care Conversations. *Journal of palliative care.* 2018;33(3):143-148.

34. Yates P, Bloomer M, Bartley J, et al. Achieving Quality Palliative Care for All: The Essential Role of Nurses-A White Paper by ACN 2019. 2019.

35. Evaluating Stakeholder-Identified Barriers in Accessing Palliative Care at an NCI-Designated Cancer Center with a Rural Catchment Area. 2015;18(7):634-637.

36. Bruera E, Hui DJJoCO. Integrating supportive and palliative care in the trajectory of cancer: establishing goals and models of care. 2010;28(25):4013-4017.

37. Davis MP, Strasser F, Cherny N. How well is palliative care integrated into cancer care? A MASCC, ESMO, and EAPC Project. *Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer.* 2015;23(9):2677-2685.

38. Ferrell BR, Chung V, Koczywas M, Smith TJ. Dissemination and Implementation of Palliative Care in Oncology. *Journal of Clinical Oncology.*0(0):JCO.18.01766.

39. Finlay E, Rabow MW, Buss MK. Filling the Gap: Creating an Outpatient Palliative Care Program in Your Institution. 2018(38):111-121.

40. Hui D, Cherny N, Latino N, Strasser F. The 'critical mass' survey of palliative care programme at ESMO designated centres of integrated oncology and palliative care. *Annals of oncology : official journal of the European Society for Medical Oncology.* 2017;28(9):2057-2066.

41. Hui D, Cherny NI, Wu J, Liu D, Latino NJ, Strasser F. Indicators of integration at ESMO Designated Centres of Integrated Oncology and Palliative Care. *ESMO open.* 2018;3(5):e000372.

42. Hui D, De La Rosa A, Chen J, et al. Growth of palliative care (PC) in United States cancer centers: A national survey. In: American Society of Clinical Oncology; 2019.

43. Hui D, Elsayem A, De la Cruz M, et al. Availability and integration of palliative care at US cancer centers. *JAMA.* 2010;303(11):1054-1061.

44. Kamal AH, Bull JH, Swetz KM, Wolf SP, Shanafelt TD, Myers ER. Future of the Palliative Care Workforce: Preview to an Impending Crisis. *The American Journal of Medicine.* 2017;130(2):113-114.

45. Kaufmann TL, Kamal AH. Oncology and Palliative Care Integration: Cocreating Quality and Value in the Era of Health Care Reform. *Journal of Oncology Practice.* 2017;13(9):580-588.

46. Morrison RS, Augustin R, Souvanna P, Meier DEJJopm. America's care of serious illness: a state-by-state report card on access to palliative care in our nation's hospitals. 2011;14(10):1094-1096.

47. Rocque GB, Mullvain JA, Eickhoff J, Cleary JF, Campbell TC. Integrating palliative care into the oncology clinic: A joint management approach. *Palliative medicine.* 2016;30(5):510-512.

48. Dunn S, Earp MA, Biondo P, et al. Oncology Clinicians' Challenges to Providing Palliative Cancer Care—A Theoretical Domains Framework, Pan-Cancer System Survey. *Current Oncology.* 2021;28(2):1483-1494.

49. Desai AV, Klimek VM, Chow K, et al. 1-2-3 project: a quality improvement initiative to normalize and systematize palliative care for all patients with cancer in the outpatient clinic setting. *Journal of oncology practice.* 2018;14(12):e775-e785.

50. Becker CL, Arnold RM, Park SY, et al. A cluster randomized trial of a primary palliative care intervention (CONNECT) for patients with advanced cancer: protocol and key design considerations. *Contemporary clinical trials.* 2017;54:98-104.

51. Schmalz OO, Jacob C, Ammann J, et al. 85P - Impact of digital patient monitoring (DPM) on quality of clinical care of cancer immunotherapy (CIT)-treated patients (pts) with advanced/metastatic non-small cell lung cancer (a/mNSCLC). *Annals of Oncology.* 2019;30:xi30-xi31.

52. Nair R, Kohen SA. Can a patient-directed video improve inpatient advance care planning? A prospective pre-post cohort study. *BMJ Quality & Safety.* 2019;28(11):887.

53. Liu M, Cardenas V, Zhu Y, Enguidanos S. YouTube videos as a source of palliative care education: a review. *Journal of palliative medicine.* 2019;22(12):1568-1573.

54. Sedhom R, Gupta A, Shah M, et al. Oncology Fellow–Led Quality Improvement Project to Improve Rates of Palliative Care Utilization in Patients With Advanced Cancer. *JCO Oncology Practice.* 2020;16(8):e814-e822.

55. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A. Making psychological theory useful for implementing evidence based practice: a consensus approach. *BMJ Quality & Safety.* 2005;14(1):26-33.

56. Michie S, Van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implementation science.* 2011;6(1):1-12.

57. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation science.* 2012;7(1):1-17.

58. Atkins L, Francis J, Islam R, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implementation Science.* 2017;12(1):1-18.

59. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation Science.* 2015;10(1):1-14.

60. Jensen RE, Moinpour CM, Potosky AL, et al. Responsiveness of 8 Patient-Reported Outcomes Measurement Information System (PROMIS) measures in a large, community-based cancer study cohort. *Cancer.* 2017;123(2):327-335.

61. Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implementation Science.* 2017;12(1):108.

62. Haun J, Luther S, Dodd V, Donaldson P. Measurement variation across health literacy assessments: implications for assessment selection in research and practice. *J Health Commun.* 2012;17 Suppl 3:141-159.

63. Badr H, Smith CB, Goldstein NE, Gomez JE, Redd WH. Dyadic psychosocial intervention for advanced lung cancer patients and their family caregivers: Results of a randomized pilot trial. *Cancer.* 2015;121(1):150-158.

64. Guest G, Bunce A, Johnson L. How Many Interviews Are Enough?: An Experiment with Data Saturation and Variability. *Field Methods.* 2006;18(1):59-82.

65. Green J, Thorogood N. *Qualitative Methods for Health Research.* 4th ed. Thousand Oaks, CA: Sage; 2018.