PROTOCOL AMENDMENT #2

LCCC 2150: Families Addressing Cancer Together (FACT): A Pilot Randomized Controlled Trial

AMENDMENT INCORPORATES (check all that apply):

_x_ Editorial, administrative changes
_x_ Scientific changes (IRB approval)
___ Therapy changes (IRB approval)
___ Eligibility Changes (IRB approval)

AMENDMENT RATIONALE AND SUMMARY:

Editorial changes

(I) The version number and date have been changed throughout the document.
(II) We have updated the PI name throughout the document.
(III) Neda Padilla and Savannah Bowers have been removed as protocol co-coordinators.
(IV) Yesy Lopez has been added as a protocol coordinator.

Scientific changes

(I) We have added Dr. Zev Nakamura as Principal Investigator to replace Dr. Eliza Park.

LCCC2150: Families Addressing Cancer Together (FACT): A Pilot Randomized Controlled Trial

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LCCC2150: Families Addressing Cancer Together (FACT): A pilot randomized controlled trial

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Signature Page

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations and ICH guidelines.

Principal Investigator (PI) Name: __Zev Nakamura MD_____

PI Signature: _____

Date: _____March 31, 2023_____

Version Date: _____March 31, 2023_____

Master Protocol – Summary of changes from previous version

Version	V. Date	Revision summary	PRC status	IRB status
1.0	11/12/21	n/a – Initial submission	Submitted 11/19/21	Approved 2/23/22
2.0	02/22/22	1. Updated duration of measures 2. Replace PHQ-9 with PHQ-2 3. PHQ suicidality monitoring 4. Removed FACT-G measure 5. Replaced PCCQ with updated wording 6. Replaced 15-item parent-child relationship quality measure with single-item measure 7. Replace demographic form 8. Added Neda Padilla and Michelle Manning added as coordinators	Submitted 2/22/22	Approved
3.0	3/31/23	1. Added Dr. Zev Nakamura as PI, Yesy Lopez as study coordinator 2. Removed Savannah Bowers and Neda Padilla as coordinators	Submitted	Submitted

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1.0 BACKGROUND AND RATIONALE

1.1 Study Synopsis

This is a single center, two-arm pilot randomized controlled trial (RCT) evaluating the feasibility and acceptability of a novel psychosocial intervention, Families Addressing Cancer Together (FACT) delivered as a mobile response web application (mobile web app). FACT is a theory-guided, psychoeducational intervention designed to improve parents' confidence and ability to talk about their cancer with their minor children. We will enroll 40 patients with cancer who have a minor child to participate in this 6-week study. The primary hypothesis being tested is that an intervention that assists parents with their communication needs with their children can be feasible, acceptable, and improve parental communication self-efficacy when compared with a waitlist control condition. Findings from this study will inform a future grant application to further test this intervention in a randomized full efficacy trial.

1.2 Background

Parents with cancer are encouraged to be "honest and open" with their minor children about their illness. Yet, for the nearly two million US parents facing a new cancer diagnosis and treatment,[1] most will receive minimal guidance from their oncology or psychosocial oncology providers for this difficult task. For parents with cancer, the disease creates major disruptions to the family unit, threatens parents' desire to protect their children from harm, and leads to substantial depression and anxiety.[2,3] Concerns about communication with children contribute to this heightened distress: parents report uncertainty about what to tell their children, the optimal timing of disclosure, and how to provide developmentally appropriate, emotionally-charged information.[4,5] For parents with advanced disease, discussing life-limiting prognoses are particularly challenging. Parental communication about illness is linked to better emotional adjustment for both themselves and their children,[6-8] yet most cancer centers lack the resources to address these patients' needs. Lay publications to support parental illness communication exist, but patients prefer tailored resources specific to their concerns and disease.[9,10]

The few evidence-based interventions to facilitate parental cancer communication demonstrate high acceptability, yet are limited by the need for extensive infrastructure or highly specialized providers, thus limiting dissemination. What remains unknown is how to deliver timely, customized parental communication guidance across cancer treatment settings. Without this support, parents with cancer and their children experience avoidable psychosocial distress. In order to better support parental communication needs in cancer, psychosocial interventions that can be implemented across clinical practice settings are needed.

To address this gap, we have developed FACT – a theory-guided, psycho-educational intervention to help parents with cancer talk about their illness with their children in a developmentally appropriate way. We designed FACT to be responsive to parents'

concerns and communication goals and to support nuanced communication that considers parents' disease, treatment, prognosis, and maturity of their child. FACT accomplishes this customization via computer-tailored algorithms and >1000 message library. Parents complete a separate tailoring assessment for each child, allowing FACT to generate child-specific content. FACT pairs educational content with conversation scripts ("words you can use") –user-tested examples for introducing complex or emotionally intense information. As a mobile responsive web application, FACT can be used with a variety of devices.

FACT was developed through an extensive review of the scientific literature and publicly available resources, consultation with mental health, social work, oncology, and palliative care clinicians, patient and caregiver stakeholder interviews, and data from the PI's prior observational studies with parents living with cancer.

1.3 Purpose and Rationale

This pilot study will provide the necessary data to inform the development and full efficacy testing of a novel psychosocial intervention to support parents with cancer in communicating with their children about cancer. The research questions to be answered by this study are whether the intervention being tested can be feasible, be acceptable, and provide preliminary estimates of improvement in parental communication and psychological outcomes as compared to a waitlist control condition.

2.0 STUDY OBJECTIVES

2.1 Primary Objective

The primary objective of this study is to evaluate the acceptability of FACT when delivered as a mobile web app. Acceptability will be defined through participant satisfaction ratings and analysis of semi-structured interview data.

2.2 Secondary Objective

A secondary objective of this study is to evaluate the feasibility of the study and study procedures in preparation for a future efficacy RCT of the intervention. We will report on participant screening, recruitment, and retention.

2.3 Exploratory Objectives

[redacted]

3.0 PATIENT ELIGIBILITY

3.1 Inclusion Criteria

Confirmation of eligibility criteria is required for all potential study participants prior to study enrollment. Participants will be eligible for study participation as defined by the inclusion and exclusion criteria as follows:

3.1.1. Informed consent reviewed and signed;
3.1.2. Age equal to or above 18 years;
3.1.3. Ability to understand and comply with study procedures;
3.1.4. Able to complete all study measures and visits in English;
3.1.5. Be a parent (defined as biological, adoptive, foster, or step-parent), kin caregiver (defined as a relative or someone with a significant emotional relationship who provides full-time care and nurturing of a child), or legal guardian of a child age 3 to 17 years of age who can speak and understand English;
3.1.6. Have a diagnosis of Stage II-IV (or equivalent) invasive solid tumor not in surveillance or survivorship

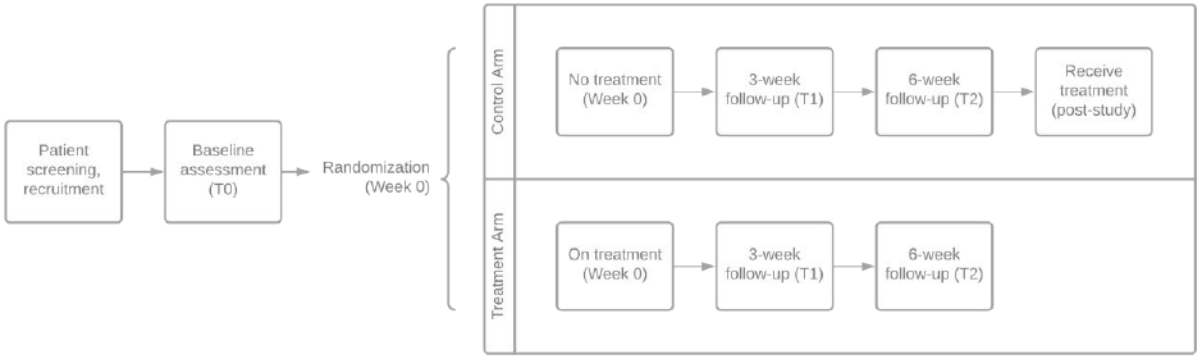
3.2 Exclusion Criteria

Eligible participants must not have any of the following to be enrolled in the study.

3.2.1 Unable to complete self-report instruments due to illiteracy, neurologic illness, inability to speak or read English, or other causes;
3.2.2 Prior participation in the pilot trial (LCCC2030) or development and user testing protocol (LCCC1952) preliminary to this study;
3.2.3. No current or expected contact with their child; or
3.2.4. Existence of other co-morbid disease, which in the opinion of the investigator, prohibits participation in the protocol.

4.0 STUDY PLAN

4.1 Schema



This is a two-arm, randomized controlled trial of 40 patients with cancer who are parents of minor children. Participants will be approached in hospital or clinic settings, complete

baseline assessments, randomized to intervention (FACT) vs. control (waitlist control), and complete follow-up assessments 3-weeks post-randomization and 6-weeks post-randomization. Study visits will occur at NCCH, via telephone, or secure video. We anticipate enrolling participants over a six-month period and that active participation will last for a 2-month period.

4.2 Duration of Study

The duration of individual participation is estimated to be two months per participant. Individual study participation is expected to consist of enrollment, baseline assessment, assignment to treatment arms, and two follow-up assessments inclusive of surveys and a semi-structured interview.

4.2.1 Baseline assessment (T0):

Based on our prior survey-based research studies, we anticipate the baseline assessment questionnaire to last approximately 10-15 minutes.

4.2.2 Treatment assignment:

Participants assigned to the study intervention will receive access to the online portal within which they can create and review their customized communication guidance. We anticipate that the creation process will last 5-10 minutes. Participants' access will be maintained throughout the course of their participation; as such, duration and frequency of active interaction with intervention assessments will be completely at the discretion of each individual participant.

4.2.3 3-week follow-up assessment (T1):

The 3-week post-intervention assessment consists of structured surveys, which we estimate will take approximately 10-15 minutes.

4.2.4 6-week follow-up assessment (T2):

The 6-week post-intervention assessment consists of structured surveys and a semi-structured interview with each participant to provide feedback on the intervention (if assigned to the treatment arm) and study procedures (both arms). The interview is expected to last approximately 30 minutes. The surveys will take approximately 10-15 minutes.

4.3 Study Details

4.3.1 Pre-study Assessments

4.3.1.1 Screening

We will use the screening procedures in place for Dr. Park's LCCC2030 study, "A Pilot Study of the Families Addressing Cancer together (FACT) Tool." Potential study participants will be identified through conversations with the participant's attending oncologists or Comprehensive Cancer Support Program (CCSP) consulting clinicians, review of outpatient multidisciplinary and hematology/oncology clinic patient rosters, review of radiation oncology and chemotherapy infusion room rosters and review of inpatient oncology service rosters or oncology consultation service rosters. We will request a waiver of HIPAA authorization to conduct this screening because of the high percentage of patients with cancer at UNC who might not be eligible for the study due to their age or disease status.

4.3.1.2 Recruitment and informed consent

The PI and other members of the research team will identify eligible patients through electronic medical record (EMR) review and receive permission from the patient's oncology clinician(s) before approaching eligible patients. As such, patients whom the oncology team believes are at high risk of emotional distress from study participation will not be approached. All participants will provide informed consent for the study and HIPAA authorization. Copies will be given to participants, and signed forms will be kept locked in the office of the PI or study coordinator. When approaching an eligible patient, the research team member will describe the nature of the study questions and their purposes and written or electronic informed consent will be sought.

When the treating oncology team believes it may be more acceptable to an individual patient, a member of the oncology team may first introduce the study. The provider will briefly describe the study, provide an approved brochure to the patient, and assess willingness to be contacted by the study team.

In addition to in-person recruitment, recruitment will occur by telephone. This method of recruitment will be used to recruit potential participants when in-person recruitment is unfeasible or restricted (e.g., due to COVID-19). This method will also be used to recruit potential participants who express interest in the study but who do not provide written or electronic informed consent at the time of initial in-person recruitment. As with in-person recruitment, telephone recruitment will only occur after receiving healthcare clinician permission to approach the patient and verbal statements from the patient that the study team can call them to further discuss the study. Patients who cannot be reached by phone after three attempts will receive an email, if applicable, from the study team. The content of any such email will be limited such that only the following information will be disclosed: the caller's name, that he/she/they is calling to follow up about a UNC research study, and staff contact information.

Participation in this study is voluntary. Patients who choose not to participate in this study will not be subject to prejudice in the delivery of health care by their physicians and clinical staff nor by the research institution. The informed consent discussion will occur with a trained member of the research team and will include review of the purpose of the

research, procedures, risks, benefits, and participant's rights. Study participants can contact the PI to address all questions both prior to and after consenting to participate in the study. All participants will be specifically reminded that they may withdraw at any time without impacting their treatment or relationship with their clinical team and that they may choose not to answer any study questions they would rather not answer, with exception to the tailoring questionnaire items used to generate their intervention materials.

Items in the tailoring questionnaire will be forced-response, as missing items would result in the study intervention being unable to generate participants' materials. Participants will be told during the informed consent process that those specific items will be forced-response, will have the opportunity to preview the items before consenting if desired, and will be informed as to the rationale for making these items forced-response. The consenting study team member will reaffirm that all other study questions may still be skipped if preferred.

4.3.2 Study assessments

4.3.2.1 Baseline study assessment (T0)

After receiving consent, each participant will be assigned a unique and random study ID. All data collected will be associated only with this ID. The research team member will then obtain baseline assessment information from the participant. Participants will complete the study forms online via a secure REDCap link or with pen and paper.

The baseline study assessment consists of a demographic form and several patient-reported outcome measures. See the Study Measures section and Appendices for details about the measures and how they will be administered. Baseline assessments must be completed before randomization.

4.3.2.2 Randomization

Participants will be randomized to one of two arms: (1) intervention arm, or (2) control arm. Participants will be assigned with an allocation ratio of 1:1 and stratified by disease status: advanced (stage IV or equivalent) vs non-advanced. This will be implemented through REDCap's randomization module which will directly follow entry of baseline data. Setup of the randomization module will be done only by the PI or CRC, and the study biostatistician will confirm that the randomization scheme logic is functional before any data is collected. This logic will be preserved such that group assignment cannot be altered or manipulated when accrual begins.

Given the nature of this study, a double-blind design is not possible as both the participants and recruiting staff will be able to easily infer group assignment.

4.3.2.3 Intervention arm (FACT)

The FACT intervention is an interactive mobile responsive web application that provides personally tailored communication guidance to parents with cancer to help them talk about their illness with their minor children.

Upon accessing the mobile responsive web application, participants will be prompted to enter their study ID and then complete a tailoring assessment. The assessment addresses child and family characteristics, the participant's disease characteristics, their communication goals, communication concerns, and prior communication experiences. Using study-specific computer tailoring algorithms, the web application then provides the participant with customized communication feedback. Participants complete the tailoring assessment individually for each child for which they seek customized feedback, however, they will be asked to complete outcome measures in reference to one selected child. Throughout the study period, the participant can access the web application at a frequency, duration, and timing of their choosing and may re-take the assessment to receive updated information. They will not provide identifiable data via the web application but they can choose to save their data for later review. Participants will be informed that the research team will monitor user-log metadata (e.g., log ins, webpage views) and that the participant may occur data charges related to their use of the FACT web application based on their individual data plan.

Inclusion of participants for whom barriers to internet access exist
For participants who lack reliable home internet access, we will offer in-hospital use of a password-protected study tablet to access the intervention. These participants will have the opportunity to print their customized materials and/or re-use the study tablet during subsequent hospital visits.

Check-in phone call or message
No more than one week after a participant has received access to the online FACT portal, a member of the study team will contact the participant via their preferred communication method. This will serve the purpose of quickly identifying and resolving any login or other issues should a participant experience them.

Forced-response items
All tailoring items within the online intervention interface will be forced-response, as missing items would result in the being unable to generate participants' tailored materials. This will be clearly disclosed during the informed consent process and in informed consent documents as described above.

4.3.2.4 Control arm (Waitlist control)

Participants in the waitlist control condition will receive their usual care – which includes access to the UNC CCSP (for which the PI serves as the Deputy Director of Clinical Operations) by clinician- or self-referral. A waitlist control model allows the research team to collect maximally rigorous data while addressing the ethical considerations of completely withholding the study intervention from participants assigned to this arm.

These individuals will participate on the same schedule as the treatment arm but receive the study intervention after their data collection activities are complete. Given the elevated psychological distress that parents with cancer experience and the low risk profile of the protocol, use of a waitlist control group is appropriate.

4.3.2.5 3-Week Follow-up assessment (T1)

Participants will complete follow-up surveys via secure REDCap link or pen-and-paper.

4.3.2.6 6-Week Follow-up assessment (T2)

Participants will complete follow-up surveys via secure REDCap link or pen-and-paper.

The post-intervention semi-structured interview may be conducted in person at NCCH, by telephone, or by secure video. The interview content will ask participants to discuss barriers and facilitators to intervention use, desired communication content areas not addressed in the current communication tool (treatment arm only), feedback on their experiences communicating with their children, opinions on study procedures, suggestions for improvement to the intervention and/or study activities, and any psychosocial follow-up needs. The interview is expected to last approximately 30 minutes and will be conducted by a member of the study team with training in conducting such research interviews with patients. Participants are not required to answer questions they find emotionally distressing and are reminded of this right prior to beginning the interview. All interviews will be audiotaped and then transcribed for analysis.

4.3.3 EMR abstraction

Research team members will abstract basic data from the EMR about participants' eligibility, demographics, cancer and its treatment, and cancer support intervention use.

To facilitate screening procedures, research staff will obtain information about patients' parental status and cancer type and stage through review of the EMR. EMR data will be stored electronically on the REDCap database for the duration of study recruitment so that we do not re-contact individuals whom we have previously identified as ineligible or who decline study participation. Following the conclusion of study recruitment, this information will be destroyed. For participants who enroll in the study, research staff will additionally collect information on their cancer and its treatment and supportive care intervention use after obtaining HIPAA Authorization for research.

4.3.4 Intervention usage metrics

For participants in the intervention condition, the password-protected, mobile responsive web application created by CHAI (Connected Health for Applications and Interventions) Core at UNC will track user-log metadata such as number of user log ins, session duration and pages accessed. This data will be stored electronically on the CHAI Core at UNC secure server.

4.3.5 Self-report measures

Participants will complete several outcome measures. Participants may complete some or all of the surveys and can skip any questions they find distressing.

The measuring instruments, schedule of administration, and estimated duration are listed in Table 1.

Table 1. Measuring instruments

Domain	Measure	Time (min)	Arm	Schedule
Demographic form	Demographic form	2	Both	T0
Performance status	Eastern Cooperative Oncology Group Performance Status Scale (ECOG)	1	Both	T0
Illness beliefs	Two items, Investigator-designed, minimally adapted for this study	1	Both	T0
Parental cancer communication beliefs & behaviors	Parental Cancer Communication Questionnaire (PCCQ)	5	Both	T0, T1, T2
Anxiety symptoms	Generalized Anxiety Disorder – 7 (GAD-7)	3	Both	T0, T1, T2
Depression symptoms	Patient Health Questionnaire-2 (PHQ-2)	1	Both	T0, T1, T2
Communication self-efficacy	Communication Self-Efficacy Scale (CSES)	3	Both	T0, T1, T2
Parent-child relationship	Single-item assessment, adapted from Sandler, et al.	1	Both	T0, T1, T2
Acceptability	FACT Satisfaction scale	3	Treatment	T1, T2
Other resource use	Investigator-designed, single item	1	Both	T0, T2

4.3.5.1 Demographic form

The investigator-designed demographic form (see Appendix A) is a brief self-administered questionnaire that includes questions such as age, race/ethnicity, education, family composition, and marital status. Based on the PI's prior studies, the average time to complete the measure is estimated to be 2-3 minutes.

4.3.5.2 Eastern Cooperative Oncology Group Performance Status Scale (ECOG)

The ECOG evaluates the severity of symptoms and amount of assistance the participant requires to complete "normal activities" using a 5-point scale (see Appendix B). The ECOG is used to assess how the disease affects the daily living abilities of the patient and determine appropriate treatment and prognosis.[11] It has been modified for patient self-report.

4.3.5.3 Illness beliefs

Two questions assessing participants' appraisals of illness severity, adapted from Compas, et al. (see Appendix B).[12]

4.3.5.4 Parental Cancer Communication Questionnaire (PCCQ)

Participants will be asked up to 26 investigator-designed questions assessing their parental communication concerns (appraisals), their beliefs about anticipated

consequences of discussions with their children about cancer (outcome expectancies), and their communication behaviors with their children. Parents who have engaged in any communication with their children about cancer will also be asked questions about their child(ren)'s response to these discussions (see Appendix C). The estimated time to complete these items is 5-7 minutes.

4.3.5.5 Generalized Anxiety Disorder – 7 (GAD-7)

The GAD-7 is a common measure of anxiety consisting of 7 items (Appendix D). The scale captures the elements of thoughts, emotions, and physical symptoms associated with general anxiety. The GAD-7 is very well-validated for the general population in addition to use for clinical assessment (e.g. psychiatric disorders). Items are scored on a four-point Likert scale with responses scores ranging from 0 (low/no anxiety) to 3 (high anxiety). Scores about 10 are considered to be clinically significant for anxiety.[13] The estimated time to complete this measure is no more than 5 minutes.

4.3.5.6 Patient Health Questionnaire – 2 (PHQ-2)

The PHQ-2 is a brief, well-validated measure of severity of depression symptoms and is used extensively in clinical and research settings (Appendix E).[14] Participants are asked to respond to 2 items, respectively measuring depressed mood and anhedonia, and indicate the extent to which they were bothered by that symptom in the two weeks prior to the questionnaire. Items are Likert-type and have response options of 0 ("not at all"), 1 ("several days"), 2 ("more than half the days"), and 3 ("nearly every day"). The estimated time to complete this measure is no more than 1 minute.

4.3.5.7 Communication Self-Efficacy Scale (CSES)

The nine-item CSES is adapted from Murphy et. al.'s maternal HIV disclosure self-efficacy scale[16] (see Appendix G). Participants rate nine statements assessing their level of confidence in their ability to tell their child about their diagnosis using a visual analogue scale. This scale has been extensively used in the parental HIV communication literature. In prior studies the Cronbach's alpha for the scale was 0.90.

4.3.5.8 FACT Satisfaction scale

The intervention satisfaction assessment is composed of six investigator-designed question items assessing the relevance and acceptability of the study intervention (see Appendix H) and a single free text question for suggestions. Participants rate each item on a 4-point ordinal scale ranging from 0 to 3. The questions have been adapted from other assessments of psychosocial intervention satisfaction/acceptability in the literature. The estimated time to complete these items is 2 minutes.

4.3.5.9 Single-item Parent-child relationship quality assessment

Single item assessing participants' perceived relationship closeness with their child. This item is adapted from Sandler, et al. in their family intervention studies. We selected this item in lieu of longer measures to minimize participant survey burden. The estimated time to complete this item is no more than 1 minute.

4.3.5.10 Other resource use

Single item assessing participants' use of informal and professional resources with respect to their communication with their children (Appendix J). The estimated time to complete this question item is one minute.

4.3.5.11 Follow-up interview

Participants will participate in a semi-structured interview with a member of the study team to obtain feedback on the intervention (see Appendix K). If participants assigned to the treatment arm elect to withdraw prior to receiving the study intervention, they will remain eligible to participate in this interview. The post-intervention interview will occur face-to-face in a private room of NCCH, via telephone, or secure video. The interview is expected to take 30 minutes. Participants are not required to answer questions they find emotionally distressing and are reminded of this right before beginning the interview. All interviews will be audiotaped and then transcribed. Interview audio files and transcripts will be stored in a password-protected file within an electronic firewall-secured server maintained by the UNC School of Medicine. Audio files will be immediately uploaded post-interview and then immediately erased from the external audio recorder. Audio files will be completely erased at study closure.

4.3.6 Post-study Assessments

None. Participants who participate in this study will not be eligible for the anticipated randomized controlled trial that will formally test the efficacy of the intervention.

4.4 Compensation

Participants will be compensated for completing study assessments. Study compensation is structured such that participants will receive $20 for completing T0, $20 for completing T1 assessments, and $20 for completing T2 survey assessments. Participants will also receive an additional $20 for completing the semi-structured interview at T2 for a maximum total of $80. In the event of early discontinuation, compensation will be pro-rated according to the above schedule.

4.5 Expected Risks

The primary risks in this study are a loss of privacy, loss of patient confidentiality, and the risk of emotional distress elicited during the interviews.

Loss of privacy

Approaching patients about enrollment in the clinic poses a risk to privacy. We expect this risk to be low. In the UNC ambulatory oncology clinics, research staff routinely approach patients for enrollment in clinical studies, and members of our team have completed prior survey and interview-based studies and psychosocial intervention clinical trials with careful attention to patient privacy and high acceptability on the part of participants. Approaching patients via telephone also poses a risk to privacy although we expect this risk to be low. Our research team has successfully approached patients about enrollment via telephone with attention to patient privacy and high acceptability on the part of participants.

Loss of confidentiality

Loss of confidentiality could occur if the study database was breached. This risk will be minimized with numerous steps to protect confidentiality (see Adequacy of Protection Against Risks, below). The alternative of not keeping identifiable information is not possible, because we will need to access the medical record to obtain illness information.

Risk of emotional distress

All eligible participants for this study will have or recently had a diagnosis of cancer – illnesses that are frequently associated with emotional, physical and spiritual distress. Eligible participants may be at higher risk for brief additional emotional discomfort or distress due to this study. Questions about communication concerns may be temporarily uncomfortable or distressing for some participants. We expect the risks of discomfort or distress to be low relative to the overall distress that the patients experience due to their serious illness. We have successfully conducted studies evaluating psychological distress, treatment decision-making, communication, prognostic understanding, and supportive care needs with parents with cancer. Participants with a wide range of educational backgrounds, illness severity, and psychological adjustment have described our study practices as appropriate and acceptable.

4.6 Adequacy of Protection Against Risks

Recruitment and informed consent

The research team will receive permission from the patient's oncology clinician(s) before approaching any eligible patients. As such, patients whom the oncology team believes are at high risk of emotional distress from study participation will not be approached. All participants will provide informed consent for the study and HIPAA authorization. Copies will be given to participants, and signed forms will be kept locked in the PI's office. When approaching an eligible patient, the research team member will describe the nature of the study questions and their purposes and written informed consent will be sought. For telephone recruitment, participants will provide study and HIPAA consent electronically through secure Qualtrics link. A copy of the consent form and HIPAA form will be emailed to participants who wish to retain a copy for their own records.

Participation in this study is voluntary. Patients who choose not to participate in this study will not be participant to prejudice in the delivery of health care by their physicians

and clinical staff nor by the research institution. The informed consent discussion will occur with a trained member of the research team. The informed consent process will include review of the purpose of the research, procedures, risks, benefits, and participant's rights. Study participants can contact the PI to address all questions both prior to and after consenting to participate in the study. All participants will be specifically reminded that they may withdraw at any time without impacting their treatment or relationship with their clinical team and that they may choose not to answer any study question they would rather not answer.

All members of the study team will undergo and maintain training in the responsible conduct of research.

Protection against loss of privacy

All study-related interactions will be conducted in private spaces at UNC Hospital or clinics or via telephone or secure video after ascertaining with the participants that their location is private. Per UNC IRB guidelines, we will use unencrypted communication (e.g., text messages) for survey reminders only if participants separately provide consent for this communication modality. We will use the UNC Transmission of Sensitive Information Standard's exception requirements for obtaining consent.

Protection against the risk of a loss of confidentiality

We will take several steps to mitigate this risk. All research staff will be thoroughly trained in the need to maintain strict confidentiality. Data will be reported in aggregate form only. All participants are assigned a unique study identifier and all participant-identifying information on paper will be kept in locked files accessible only to research staff. All electronic information will be password protected. No information obtained during the study will be used for any purpose other than the purpose for which the person has consented. The physical risks of the study procedures are minimal and the potential risks have been outlined above. The clinical care of any given participant will be handled entirely by the participant's oncologist, unless emergency care is needed due to suicidality (detailed below), and study participants will be made aware of this at the time of enrollment. Similarly, any medical problem that arises during study participation will be referred to the participant's oncology provider.

Only the research team will have access to identifiable information or to the study database. The study database will be password-protected and housed on a HIPAA-compliant, secure server at the NC TraCS Institute at UNC that are only accessible to IRB-approved personnel. The investigators and research staff will only access the database through encrypted, password-protected computers. Research staff will transport paper surveys and consent forms from the clinic to the locked office of the PI immediately after clinic and will conduct all data entry of pen-and-paper documents in the office. Surveys and consent forms will be kept in a locked cabinet in the locked office of the PI and will be destroyed upon study completion.

Protection against the risk of emotional distress or discomfort

When discussing the study with eligible patients, research staff will describe the nature of the study questions and intervention and their purposes. We will take several measures to reduce the risk of emotional distress that may occur in some study participants. First, as described above, a member of the research team will receive permission from a patient's oncology clinician before approaching them. As such, patients whom the treating oncology clinician believes are at high risk of emotional distress from study participation will not be approached. Second, research staff who have direct contact with participants will undergo training by the PI and Co-Investigator, Dr. Yopp, on how to assess and respond to participant distress. Both Drs. Park and Yopp are experienced mental health professionals who frequently provide clinical care for seriously ill patients with emotional distress. Third, participants complete measures of psychological distress, including the Patient Health Questionnaire-2 (PHQ-2) during the baseline and follow-up assessments.

In the unlikely event that a participant verbally endorses suicidality during study-related interactions, research staff will immediately contact the PI (Dr. Rosenstein if she is unavailable). Fourth, if adverse events during or between study visits such as the unlikely event of severe emotional distress occur, they will be reported to the IRB by the PI—a board-certified psychiatrist with specialized training in psycho-oncology, and the participant's primary oncologist will be notified. Should research staff observe emotional reactions necessitating clinical intervention, the study participant will be offered support services in the form of psycho-oncology assessment by a trained member of the UNC CCSP psycho-oncology service which Co-Investigator, Dr. Yopp, oversees.

The PI will individually monitor the data continuously to ensure the safety of the participants. The PI will also monitor data through weekly meetings with research staff and monthly group meetings of key study personnel. This trial will be audited by the LCCC every six to twelve months per the audit committee's guidelines and assigned a LCCC Data Safety Monitoring Committee (DSMC) per Lineberger guidelines.

4.7 Removal of Patients from Protocol

Participants will be removed from the study when any of the criteria listed in Section 3.2 apply or the participant elects to withdraw from the study. If this occurs, the PI will be notified and the reason for study removal and the date the participant was removed will be documented in the Case Report Form.

In order to support the statistical integrity of analyses, the pre-randomization discontinuation of any participant will trigger the recruitment and enrollment of an additional participant. Participants who discontinue after randomization will not be "replaced" in this manner.

5.0 TIME AND EVENTS TABLE

5.1 Time and Events Table

	Pre-study	**Baseline assessment (T0)**	**Randomization** Day 0	**3-Week Follow-Up (T1)**	**6-Week Follow-Up (T2)**

		Day 0		Day 21 (± 14)	Day 42 (± 14)
EMR eligibility screening	X				
Oncology clinician approval	X				
Informed consent and enrollment	X				
Survey outcome assessments		X		X	X
Study group assignment			X		
Semi-structured interview					X
EMR abstraction		X		X	X

6.0 UNANTICIPATED PROBLEMS

6.1 Definition

As defined by UNC's IRB, unanticipated problems involving risks to study participants or others (UPIRSO) refers to any incident, experience, or outcome that:

- Is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Is related or possibly related to a participant's participation 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) related to the research than was previously known or recognized.

6.2 Reporting

Any UPIRSO that occurs during the conduct of this study and that meets all three criteria listed in 6.1 must be reported to the UNC IRB using the IRB's web-based reporting system.

7.0 STATISTICAL CONSIDERATIONS

7.1 Study Design

This is a two-arm pilot RCT testing the acceptability, feasibility, and preliminary evidence of efficacy for a novel communication intervention for parents with cancer.

The primary objective of acceptability will be measured using the 6-item satisfaction survey. Total scores range from 0-18, so a score of 12 or higher will be considered "acceptable". If the percentage of patients who report the intervention is acceptable is 75% or higher, the intervention will be considered for future testing.

7.2 Sample Size and Accrual

We will recruit 55 patients over 6 months for the proposed study, with the hope of at least 20 patients completing T1 measures. A 95% exact binomial confidence interval (CI) will

be reported for the acceptability rate (only in the intervention group), and with n=20, the CI will have precision no more than +/- 23%. If the rate is 75%, the CI will be 50.9%, 91.3%).

For qualitative interview data, sample size estimation is based on projections of the number of participants needed to reach saturation of the concept. The sample size for the proposed study is adequate for qualitative analysis and consistent with psychosocial intervention development.[18,19]

We are confident we have adequate access to the proposed sample during the study time frame. In 2019, NCCH records included 522 English-speaking adults ages 22-54 years with a stage IV solid tumor. Our screening records suggest ~60-70% NCCH patients in this age range are parents of minor children. Data from epidemiologic studies indicate that an estimated 30% of all adult breast cancer patients are parents of minor children.[1]

Based on the PI's other research studies with parents with cancer, we conservatively expect to recruit, consent, and enroll ~10 patients/month for six months. The number of eligible patients per month is higher, however we consider factors that typically lead to deferred enrollment/consent such as patient fatigue, clinic scheduling delays, and intervening medical events.

7.3 Data Analysis Plans

7.3.1 Evaluate acceptability of the intervention

To evaluate acceptability of the intervention, we will administer a satisfaction assessment to each participant after each follow-up study visit (T1 and T2) and conduct post-intervention interviews at T2. We will report the acceptability rate at T1, along with an exact 95% confidence interval.

7.3.2 Analysis of interview data

In the follow-up interviews, we will seek input from participants in the treatment arm on: (1) the relevance of intervention components; (2) intervention acceptability and tolerability; (3) language (tone and phrasing, tailoring); and (4) emotional and cultural sensitivity. Participants assigned to the waitlist control arm will be asked to discuss: (1) the relevance of the study's subject matter; (2) their experiences regarding cancer-related communication with their children; (3) their expectations of the study intervention, which will be made available at the end of their participation, and (4) perceptions of, and feedback on, study design and operations.

We will use content analysis, a widely accepted qualitative analysis approach in health research, to identify major themes from interviews.[20] The study team will review interview transcripts, coding and categorizing the data by expanding and collapsing categories until thematic saturation is reached.[21] We will use best practices for qualitative research such as member checking, and creation of an audit trail.[22] We will use this

feedback to refine the intervention prior to launching the full efficacy trial. We will use qualitative analysis software to aid with analyses. Descriptive statistics from the quantitative rating scale and qualitative interview data will be collected concurrently, analyzed separately, and the two sets of findings converged.[23]

7.3.3 Evaluate feasibility of the intervention

To evaluate feasibility of intervention, we will report the percentage of patients who are approached about the study who:

- Enroll in the intervention (percent approached)
- Complete the intervention at each time point (percent completed per visit and overall)

We will also use descriptive statistics to assess the demographic characteristics of patients who enter, remain in, and drop out of the study. Comparisons will be made using Wilcoxon Rank sum tests for continuous characteristics and Fisher's Exact tests for categorical characteristics.

In addition, we will evaluate feasibility of study procedures including:

- Number of patients screened each month
- Number of contacts necessary to enroll participants and schedule follow-up appointments
- Proportion of completed study measures at each visit

Although adverse events are unlikely, we will examine the procedures for adverse event reporting and the study teams' response should this occur.

We will use qualitative analyses of the semi-structured interview data to explore barriers and facilitators to participation, including reasons for enrollment, non-participation (e.g. fears of unintended outcomes, competing demands, etc.), ineligibility, or withdrawal and use this information to refine study procedures in preparation for a larger-scale study.

7.3.4 Explore impact of intervention on target outcomes

We will report on changes in CSES scores from pre- (T0) to post-intervention (T1, T2) . This pilot study is not designed nor powered to detect differences as the primary objectives are to evaluate the acceptability and feasibility of the intervention as compared to treatment as usual.

We will also report on changes in other patient-reported outcomes of interest including GAD-7 and PHQ-2 scores.

We will use descriptive statistics to report on the percentage of patients who engage in any communication behaviors about cancer with their children, the depth of their discussion, and their assessments of how their children responded to these conversations.

Data from this study will be used for preliminary estimates (for which the CSES will be the primary outcome measure) to power a future R01 testing the intervention. The projected effect size will be based on mean differences in SD for the CSES from this pilot study.

7.4 Data Management/Audit

The PI and study coordinator will coordinate and manage data for quality control assurance and integrity. The recorded interview data will be kept in a password-protected electronic file housed within a secure server within the UNC Department of Psychiatry of the UNC School of Medicine. Interview data will be immediately erased from external audio recorders after confirming successful transfer to the secure server. De-identified transcriptions will be entered into a qualitative analysis program which is accessed on password-protected, encrypted computers by the study team.

Several elements will be embedded within the REDCap database in order to ensure data quality and compliance. These include a "Data History" function which generates and records an audit trail for all data; therefore, all data will be recorded with a full history including values entered. Any changes to data will be recorded and specify when the change occurred, which REDCap user changed the value, and the time of the change.

As an investigator-initiated study, this trial will also be audited by the Lineberger Cancer Center audit committee every six or twelve months, depending on the participation of affiliate sites.

8.0 STUDY MANAGEMENT

8.1 Institutional Review Board (IRB) Approval and Consent

It is expected that the IRB will have the proper representation and function in accordance with federally mandated regulations. The IRB will approve the consent form and protocol.

In obtaining and documenting informed consent, the investigator will comply with the applicable regulatory requirement(s) and should adhere to Good Clinical Practice (GCP) and to ethical principles that have their origin in the Declaration of Helsinki.

Before recruitment and enrollment onto this study, the patient will be given a full explanation of the study and will be given the opportunity to review the consent form. Each consent form must include all the relevant elements currently required by federal, local, or state regulations. Once this essential information has been provided to the patient and the investigator is assured that the patient understands the implications of participating in the study, the patient will be asked to give consent to participate in the study by signing an IRB-approved consent form.

Prior to a patient's participation in the trial, the written informed consent form will be signed and personally dated by the patient and by the person who conducted the informed consent discussion. The participant will receive copies of the signed consent form(s).

8.2 Required Documentation

Fulfillment of the following documentation must precede initiation of any study procedures:

- Delegation of Responsibilities Log and study personnel training records
- Official IRB approval letter for the protocol and informed consent
- Signed CV (within 2 years) and medical or professional licensure for all study investigators; supplemental documentation, if applicable, to document investigation qualifications may be added
- Copy of the approved protocol and associated documents, including
  - Informed consent documents
  - Recruitment materials
  - Other written material to be given to study participants
- IRB roster(s) and correspondence

8.3 Registration Procedures

Once patients have consented to participate in this trial, they will be assigned a unique and random study ID to be used throughout the study. A sole file linking the study ID to the participant's identifiers will be stored on a password protected file on a secure server maintained by the School of Medicine. Physical consent forms will be kept within a locked file cabinet and office.

All participants will also be registered in Oncore™.

8.4 Adherence to the Protocol

Except for an emergency situation in which proper care for the protection, safety, and well-being of the study patient requires alternative treatment, the study shall be conducted exactly as described in the approved protocol.

8.4.1 Emergency Modifications

UNC investigators may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial participants without prior UNC IRB approval.

For any such emergency modification implemented, a UNC IRB modification form must be completed by UNC Research Personnel within five (5) business days of making the change.

8.4.2 Single Patient/Participant Exceptions

Any request to enroll a single participant who does not meet all the eligibility criteria of this study requires the approval of the UNC Principal Investigator and the UNC IRB.

8.4.3 Other Protocol Deviations/Violations

According to UNC's IRB, a protocol deviation is any unplanned variance from an IRB approved protocol that:

- Is generally noted or recognized after it occurs
- Has no substantive effect on the risks to research participants
- Has no substantive effect on the scientific integrity of the research plan or the value of the data collected
- Did not result from willful or knowing misconduct on the part of the investigator(s).

An unplanned protocol variance is considered a violation if the variance meets any of the following criteria:

- Has harmed or increased the risk of harm to one or more research participants.
- Has damaged the scientific integrity of the data collected for the study.
- Results from willful or knowing misconduct on the part of the investigator(s).
- Demonstrates serious or continuing noncompliance with federal regulations, State laws, or University policies.

If a deviation or violation occurs, study personnel will follow the guidelines below:

Protocol Deviations: UNC personnel will record the deviation in OnCore® (or other appropriate database set up for the study), and report to any sponsor or data and safety monitoring committee in accordance with their policies. Deviations should be summarized and reported to the IRB at the time of continuing review.

Protocol Violations: Violations should be reported by UNC personnel within one (1) week of the investigator becoming aware of the event using the same IRB online mechanism used to report UPIRSO.

Unanticipated Problems Involving Risks to Participants or Others (UPIRSO): Any events that meet the criteria for "Unanticipated Problems" as defined by UNC's IRB (see section 6.1) must be reported by the Study Coordinator using the IRB's web-based reporting system.

8.5 Amendments to the Protocol

Should amendments to the protocol be required, the amendments will be originated and documented by the Principal Investigator at UNC. It should also be noted that when an amendment to the protocol substantially alters the study design, potential risk to participants, or other elements a revised consent form might be required.

The written amendment, and if required the amended consent form, must be sent to UNC's IRB for approval prior to implementation. Amendments with modifications to the study design must be approved by UNC Protocol Review Committee prior to IRB submission.

8.6 Record Retention

Study documentation includes all Case Report Forms, data correction forms or queries, source documents, Sponsor-Investigator correspondence, monitoring logs/letters, and regulatory documents (e.g., protocol and amendments, IRB correspondence and approval, signed patient consent forms).

Source documents include all recordings of observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study.

Government agency regulations and directives require that all study documentation pertaining to the conduct of a clinical trial must be retained by the study investigator. In accordance with these parameters, documents should be kept on file until three years after the completion and final study report of this investigational study, with exception of interview audio files which will be deleted upon study closure.

8.7 Obligations of Investigators

The Principal Investigator is responsible for the conduct of the clinical trial in accordance with Title 21 of the Code of Federal Regulations and/or the Declaration of Helsinki. The Principal Investigator is responsible for personally overseeing the treatment of all study patients. The Principal Investigator must assure that all study site personnel, including sub-investigators and other study staff members, adhere to the study protocol and regulations and guidelines regarding clinical trials both during and after study completion.

The Principal Investigator will be responsible for assuring that all the required data will be collected and entered onto the Case Report Forms. Periodically, monitoring visits will be conducted and the Principal Investigator will provide access to his/her original records to permit verification of proper entry of data. At the completion of the study, all case report forms will be reviewed by the Principal Investigator and will require his/her final signature to verify the accuracy of the data.

9.0 REFERENCES

1. Weaver KE, Rowland JH, Alfano CM, et al: Parental cancer and the family: a population-based estimate of the number of US cancer survivors residing with their minor children. Cancer 116:4395-401, 2010

2. Nilsson ME, Maciejewski PK, Zhang B, et al: Mental health, treatment preferences, advance care planning, location, and quality of death in advanced cancer patients with dependent children. Cancer 115:399-409, 2009

3. Mack JW, Cronin A, Fasciano K, et al: Cancer treatment decision-making among young adults with lung and colorectal cancer: a comparison with adults in middle age. Psycho-Oncology 25:1085-1091, 2016

4. Hailey CE, Yopp JM, Deal AM, et al: Communication with children about a parent's advanced cancer and measures of parental anxiety and depression: a cross-sectional mixed-methods study. Support Care Cancer 26:287-295, 2018

5. Elmberger E, Bolund C, Magnusson A, et al: Being a mother with cancer: achieving a sense of balance in the transition process. Cancer Nurs 31:58-66, 2008

6. Grenklo TB, Kreicbergs UC, Valdimarsdottir UA, et al: Communication and trust in the care provided to a dying parent: a nationwide study of cancer-bereaved youths. J Clin Oncol 31:2886-94, 2013

7. Kennedy VL, Lloyd-Williams M: Information and communication when a parent has advanced cancer. J Affect Disord 114:149-55, 2009

8. Forrest G, Plumb C, Ziebland S, et al: Breast cancer in the family--children's perceptions of their mother's cancer and its initial treatment: qualitative study. BMJ 332:998-1003, 2006

9. Lustria MLA, Noar SM, Cortese J, et al: A meta-analysis of web-delivered tailored health behavior change interventions. Journal of health communication 18:1039-1069, 2013

10. Turner J, Clavarino A, Yates P, et al: Development of a resource for parents with advanced cancer: what do parents want? Palliat Support Care 5:135-45, 2007

11. Oken MM, Creech RH, Tormey DC, et al: Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-55, 1982

12. Compas BE, Worsham NL, Epping-Jordan JE, et al: When mom or dad has cancer: markers of psychological distress in cancer patients, spouses, and children. Health Psychol 13:507-15, 1994

13. Spitzer RL, Kroenke K, Williams JB, et al: A brief measure for assessing generalized anxiety disorder: the GAD-7. Archives of internal medicine 166:1092-1097, 2006

14. Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. Med Care. 2003 Nov;41(11):1284-92. doi: 10.1097/01.MLR.0000093487.78664.3C. PMID: 14583691.

15. Cella DF, Tulsky DS, Gray G, et al: The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. J Clin Oncol 11:570-9, 1993

16. Murphy DA, Armistead L, Marelich WD, et al: Pilot trial of a disclosure intervention for HIV+ mothers: the TRACK program. J Consult Clin Psychol 79:203-14, 2011

17. Pianta RC: Child-parent relationship scale. Unpublished measure, University of Virginia 11:39-41, 1992

18. Patrick DL, Burke LB, Gwaltney CJ, et al: Content validity--establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO Good Research Practices Task Force report: part 2--assessing respondent understanding. Value Health 14:978-88, 2011

19. Patrick DL, Burke LB, Gwaltney CJ, et al: Content validity--establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO good research practices task force report: part 1--eliciting concepts for a new PRO instrument. Value Health 14:967-77, 2011

20. Boeije H: A purposeful approach to the constant comparative method in the analysis of qualitative interviews. Quality & Quantity 36:391-409, 2002

21. Hewitt-Taylor J: Use of constant comparative analysis in qualitative research. Nurs Stand 15:39-42, 2001

22. Sage handbook of mixed methods in social & behavioral research. Los Angeles, SAGE Publications, 2010

23. Creswell JW, Clark VLP: Designing and conducting mixed methods research. 2007

10.0 APPENDICES

(A) Demographic form
(B) Eastern Cooperative Oncology Group Performance Status Scale and Illness Beliefs Form
(C) Parental Cancer Communication Questionnaire (PCCQ)
(D) Generalized Anxiety Disorder-7 (GAD-7)
(E) Patient Health Questionnaire-2 (PHQ-2)
(F) Functional Assessment of Cancer Therapy – General (FACT-G)
(G) Communication Self-Efficacy Scale (CSES)
(H) FACT Satisfaction Scale
(I) Single-item parent-child relationship assessment
(J) Other resource use form
(K) Semi-structured interview guide
(L) Recruitment brochure