Toward an integrated approach to assessing and addressing follow-up care needs that will facilitate care transitions for cancer survivors: A pilot study
Atrium Health Wake Forest Baptist Comprehensive Cancer Center (AHWFBCCC)
ONC-LUN-2403

Principal Investigator:	*Name and Title*	Sarah Birken, PhD Associate Professor
	Department / Section Name	Department of Implementation Science
	Email Address	[redacted]
	Phone Number	[redacted]
	Name and Title	Stephanie Sohl, PhD Associate Professor
	Department / Section Name	Department of Social Sciences and Health Policy
	Email Address	[redacted]
	Phone Number	[redacted]

Biostatistician:	*Name and Title*	Emily Dressler, PhD Associate Professor
	Department / Section Name	Department of Biostatistics and Data Science
	Email Address	[redacted]
	Phone Number	[redacted]
Study Coordinator:	*Name and Title*	Aliza Randazzo, Associate Project Manager
	Email Address	[redacted]
	Phone Number	[redacted]
Regulatory Contact:	*Name and Title*	Aliza Randazzo, Associate Project Manager
	Email Address	[redacted]
	Phone Number	[redacted]

Participating Institution(s):
Wake Forest University School of Medicine

Atrium Health Wake Forest Baptist Comprehensive Cancer Center (AHWFBCCC)

Effective Version Date: 09/30/2024

Protocol Amended Date: 4/10/2025

Confidential

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Summary

As the number of people living after a cancer diagnosis (i.e., survivors) increases, perspectives have shifted from treating cancer as a terminal to a chronic illness. High-quality chronic illness care is complex to deliver and involves collaborating with patients to ensure they have what they need to be actively engaged in their care to meet their health needs (i.e., self-manage). Supporting survivors to engage in self-management is also critical for personalizing care based on survivors' risk for late and long-term effects of cancer treatment and need for behavioral and social supportive services (e.g., psychological support, financial navigation). Thus, we will implement a multi-level SHAREDCare intervention for engaging survivors and systematically developing a personalized response to address their needs with an initial focus on one of the most prevalent cancer types among survivors (i.e., lung). SHAREDCare is designed to support the whole-person by: integrating distress and health-related social needs screenings to comprehensively address distress; incorporating a link to and understanding of importance of involving primary care providers early in cancer care; informing the survivor and engaging their partnership in care planning; developing a personalized plan for addressing comprehensive distress; and establishing how to review related data to advocate for adequate resources. Our primary aim is to pilot SHAREDCare with 15 lung cancer survivors in AHWFBCCC's lung clinic and qualitatively assess acceptability through semi-structured interviews. We will also use validated questions to assess acceptability, feasibility, and appropriateness of SHAREDCare and any impact on addressing survivor unmet needs or survivor-reported referrals.

1.0 Introduction and Background

As the number of people living after a cancer diagnosis (i.e., survivors) increases, perspectives have shifted from treating cancer as a terminal to a chronic illness.[1] High-quality chronic illness care is complex to deliver and involves collaborating with patients to ensure they have what they need to be actively engaged in their care to meet their health needs (i.e., self-manage).[2] Supporting survivors to engage in self-management is also critical for personalizing care based on survivors' risk for late and long-term effects of cancer treatment and need for behavioral and social supportive services (e.g., psychological support, financial navigation).[3-5]

Atrium Health Levine Cancer Institute (LCI) has successfully implemented Electronic Distress Screening (EDS) via Lucet, an electronic health record-integrated system-level tool for assessing and addressing behavioral and social needs (e.g., depression, transportation challenges) via iPad in <8 minutes before an appointment and automated referrals (currently used with Epic). To date, EDS has been used to assess needs in more than 63,464 LCI cancer survivors (70%) upon intake. Patients with elevated distress and malnutrition have been automatically referred for more support. Yet, there has been variability in how other needs have been reviewed or addressed. To integrate with LCI, Atrium Health Wake Forest Baptist Comprehensive Cancer Center (AHWFBCCC) plans to implement EDS in March 2024. Clinical and operational leaders anticipate many opportunities for EDS, including assessing and addressing survivors' needs at regular intervals rather than only at intake, further identifying clinical services priorities, and facilitating research.[6-10]

We propose to leverage Enterprise-wide EDS implementation to build upon our extensive preliminary research in improving cancer survivorship care and outcomes. We found that assessing and addressing behavioral and social needs is a necessary component of a AHWFBCCC intervention intended to address primarily provider-level barriers to care transitions to promote the right care in the right place at the right time for breast cancer survivors (Supporting Transitions AfteR Treatment [START], Dr. Birken, Co-Principal Investigator, implementation scientist, expertise in cancer survivorship care). Further, we found that a health self-management coaching program that supported survivorship care planning was feasible and showed promising improvements in health outcomes (Shared Healthcare Actions & Reflections Electronic Systems in survivorship [SHARE-S]; Dr. Sohl, Co-Principal Investigator, behavioral medicine researcher, focus on empowering survivor self-management). Health coaches empowered survivors in identifying strategies for overcoming patient-level barriers to meeting needs). Our prior research has also identified needs and relevant resources important later in the cancer care trajectory (which may differ from those at intake, when LCI currently uses EDS).[11] Therefore, we propose to integrate our highly complementary lines of work to optimally address cancer survivors' follow-up care needs by integrating EDS with care transitions and coaching interventions to improve survivorship care and outcomes.

We will capitalize on LCI/AHWFBCCC's strengths and opportune timing of integration to support the implementation of an integrated system for addressing critically important follow-up care needs with an initial focus on one of the most prevalent cancer types among survivors (i.e., lung).

2.0 Objectives

2.1 Primary Objective

Pilot and qualitatively assess the acceptability of SHAREDCare through semi-structured interviews

2.2 Secondary Objective

2.2.1 Describe quantitative assessments of intervention acceptability, appropriateness, and feasibility.[12]

2.2.2 Describe survivor level of unmet needs[13] using a validated measure to collect data before and/or after completion of the SHAREDCare intervention.

2.2.3 Track clinical referrals and other actions made as a result of patient responses on the EDS and the percentage of referrals that have been "completed" (i.e. those referrals where a patient completed the relevant medical or social needs-related visit).

2.2.4 Track recruitment, assessment completion, and any related adverse events.

3.0 Study Population

3.1 Inclusion Criteria

3.1.1 Patients must have histologically or cytologically confirmed study disease. A pathology report should be referenced/available (stages I-IV lung cancer).
3.1.2 Ability to understand and the willingness to sign an IRB-approved informed consent document.
3.1.3 ≥18 years of age
3.1.4 Within two years of lung cancer diagnosis
3.1.5 Able to understand, read and write English

3.2 Exclusion Criteria

3.2.1 Does not meet the above inclusion criteria

3.3 Inclusion of Women and Minorities

Adults of all genders, races and ethnicities who meet the above-described eligibility criteria are eligible for this trial. We are drawing directly from patients seen by the lung clinic and thus expect that women and minorities will be represented as is consistent with the proportion seen at the Wake Forest Baptist Comprehensive Cancer Center. Should we not meet or exceed these estimates, the PI will engage the Office of Cancer Health Equity to discuss strategies to enhance recruitment in these target populations. For this pilot study, non-English speaking patients will be excluded because the intervention content will be in English. Pending results of the pilot, a future study to determine the efficacy of translating the intervention will be proposed. The intervention is designed reduce barriers to participation with the goal of reaching all patients.

3.4 Subject Recruitment

A study staff member will approach interested patients (as recommended by a cancer center social worker and/or navigator or periodic department appointment report (DAR) provided by administrative staff within the cancer center) in person or by telephone to discuss informed consent. We will enroll approximately 15 participants over 8 months from the AHWFBCCC lung clinic who meet the inclusion criteria.

4.0 Methods

4.1 Registration Procedures

All patients entered on any AHWFBCCC trial, whether treatment, companion, or cancer control trial, **must** be linked to the study in EPIC within 24 hours of Informed Consent. Patients **must** be registered prior to the initiation of treatment.

You must perform the following steps in order to ensure prompt registration of your patient:

Patients will not be registered without all required supporting documents.

1. Complete Eligibility Checklist (Appendix A – Eligibility Checklist)
2. Complete Protocol Registration Form (Appendix B – Registration Form)
3. Send the signed Informed Consent Form, Eligibility Checklist, Protocol Registration

This protocol utilizes Reduced Review registration and eligibility will not performed by the registrar.

To complete registration process, the study team will:

- assign patient study number
- register the patient on the study

4.2 Experimental or Data Collection Methods

We will pilot SHAREDCare in a clinic that treats lung cancer within a Comprehensive Cancer Center. Results of this pilot will inform a future hybrid implementation-effectiveness trial.

4.2.1 Description of Multi-level SHAREDCare Intervention

Overall, SHAREDCare is designed to address the whole-person by: integrating distress and health-related social needs assessments to comprehensively address distress; incorporating a link to and understanding of importance of involving primary care providers in cancer care; informing the survivor and engaging their partnership in shared care planning; developing a personalized plan for addressing comprehensive distress with follow-up support; (and establishing how to review related data to advocate

for adequate resources, which is not within the scope of this protocol). This multi-level approach is guided by the 5 steps for distress screening.[14] As for addressing health-related social needs,[15] 5As for patient-centered counseling,[16] and inspired by the Veterans Affairs Whole Health initiative.[17] We will specifically engage in the following process (as documented by Intervention Checklists stored via REDCap):

1. EDS report will be shared with the patient (electronically or by printing it out in person at initial visit).
2. EDS responses will be reviewed by navigator and/or Social Worker for identified needs and completeness.
3. Navigator and/or Social Worker will discuss EDS report and other identified social needs with patient to develop a shared response plan for comprehensively addressing needs (that considers patient current behavior, beliefs, motivation, establishes a specific goal for the patient, anticipates any barriers, establishes how navigator and/or Social Worker will follow-up on needs identified including any adjustments to care and assistance) in addition to already occurring automated referrals.
4. Navigator and/or Social Worker and patient will deploy shared response plan.
5. Navigator and/or Social Worker will call patient to follow-up on plan two weeks later.[16]

Patients will be compensated up to $50 total for completing assessments before and after the intervention.

- $15 for the 1st survey completion
- $15 for the last survey completion
- $20 for the one-time interview

4.2.2 Data Collection

We will also evaluate our primary indicator of success—acceptability— through semi-structured interviews. We will use participants' feedback on SHAREDCare's acceptability, appropriateness, and feasibility, as well as proposed changes to SHAREDCare and reflections on SHAREDCare's influence on survivors' care and outcomes along with the following quantitative data to inform intervention refinement for our future trial. We will utilize a patient representative as a consultant to provide feedback on (1) our drafted patient interview guide, (2) an example of the EDS report, and (3) to help the study team interpret deidentified study results. The patient representative will not be enrolled in the study and will be compensated up to $500 in gift cards for their time. The patient representative will have no access to identifiable data.

We will use medical records and data collected via EDS to assess survivor clinical characteristics (including other relevant assessments done as part of routine care) and referrals made. Survivor-reported measures of referral completion, level of unmet needs,[13] intervention acceptability, appropriateness, and feasibility,[12] and demographics will be conducted via a REDCap survey before and/or after completion of the

SHAREDCare intervention. Survey and medical record data will also be stored in REDCap. We will track recruitment, assessment completion, and adverse events.

4.3 Study-Related Activities

	Pre-Study[a] completed by study team	Baseline Assessment completed by participant	SHAREDCare Initial Call completed by study team	SHAREDCare Follow-up Call (2 weeks after Initial Call) completed by study team	Follow-up Assessment (4 Weeks after Initial Call)
Eligible for intervention	x				
Informed consent	x				
Demographics		x			
Health visit status		x			
Clinical characteristics and referrals made (Medical Record Review by study team)					x (study team)
Intervention checklists			x	x	x (study team)
Participant-reported Referral completion					x (participant)
Level of unmet needs		x			x (participant)
Intervention Acceptability, Appropriateness, & Feasibility					x (participant)
Semi-Structured Interviews					x (participant)
Adverse events			x	x	x (study team)

[a] Pre-study requirements listed in table must be completed within 60 days prior to registration.

5.0 Outcome Measures

5.1 Primary Outcome

5.1.1 SHAREDCare's qualitative acceptability (primary indicator of success) will be assessed with semi-structured interviews.

5.2 Secondary Outcomes

5.2.1 Intervention acceptability, appropriateness, and feasibility[12] will be measured with The Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure. These are four-item measures of implementation outcomes that are often considered "leading

indicators" of implementation success.[18] Acceptability will also be assessed with 6 items regarding the patient-centeredness of communication.[19]

5.2.2 Survivor level of unmet needs will be assessed before and/or after completion of the SHAREDCare intervention using a validated measure called the Survivor Unmet Needs Survey.[13] This measure will be used to determine the prevalence and predictors of cancer survivors' unmet needs.

5.2.3 Clinical referrals made and the percentage of referrals "completed" (i.e. those referrals where a patient self-reported completing the relevant visit documented in a format adapted from another study).[20]

5.2.4 Recruitment (# participants enrolled/eligible), assessment completion, and any adverse events will be described.

6.0 Analytic Plan

6.1 Sample Size and Power

The target patient sample size is approximately n=15. Our previous work has found this number of interviews with individuals holding specific knowledge of intervention acceptability (high information power[21]) to be sufficient to obtain data saturation (i.e., subsequent interviews do not generate new themes[22]). Further, if self-reported acceptability is <4, a larger study of the intervention may not be acceptable and substantial modifications will be needed.

6.2 Analysis of Primary Outcome

We will follow established methods of ensuring rigor in qualitative design. These methods will be guided by Grounded Theory, a process using inductive coding to develop theory from data (e.g., themes relating to components, timing, or delivery of the intervention).[23]

6.3 Analysis of Secondary Outcomes

Quantitative analyses will include descriptive statistics of quantitative data on level of clinical and demographic characteristics, acceptability, appropriateness, feasibility, unmet needs, and referrals. Distributions of continuous variables (acceptability, appropriateness and feasibility outcomes) will be examined for estimation of standard deviations (SD) that will be used to inform power analysis for future studies. The number of eligible participants will be tracked and for those not enrolled, reasons will be summarized. We will calculate the frequency of any adverse events and the percent of participants who complete the follow-up visit to assess retention. We will also compare demographic characteristics and baseline scores of participants who complete the follow-up visit to those who do not via Fisher's exact tests or Wilcoxon rank sum tests as appropriate. Scores on the Survivor Unmet Needs Short Form survey at baseline and follow-up will be summarized as median (IQR, range). Changes will be tested by Wilcoxon signed-rank test.

6.4 Accrual Rate

We will enroll approximately 15 participants over about 8 months from the AHWFBCCC lung clinic who meet the inclusion criteria.

6.5 Length of Study

This pilot is expected to be completed over approximately 18 months.

7.0 Data Management

Data Collection Form	Data Storage Location
Informed consent document	Epic
Decline participation form	REDCap
Race & ethnicity verification form	OnCore
Protocol registration form	OnCore
Participant clinical data	REDCap
Surveys	REDCap
Participant Interviews	SharePoint secure folder accessible only by the study team
Adverse Events Log	REDCap

8.0 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 form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection, subject identifying information will be destroyed five years after the closure of the study through deletion from study files, consistent with data validation and study design, producing an anonymous analytical data set. 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.

9.0 Data Safety and Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

10.0 Adverse Events List and Reporting Requirements

10.1 Adverse Event List for SHAREDCare

The study is expected to have no more than minimal risk for participants.

Expected adverse experiences for the study intervention are as follows:

- Emotional distress (i.e., mild anxiety or mild depressive symptoms)

10.2 Adverse Event Characteristics

CTCAE term (AE description) and grade: The descriptions and grading scales found in the revised NCI Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 will be utilized for AE reporting. All appropriate treatment areas should have access to a copy of the CTCAE version 5.0. A copy of the CTCAE version 5.0 can be downloaded from the CTEP web site (http://ctep.cancer.gov).
'Expectedness': AEs can be 'Unexpected' or 'Expected' (see Section 8.1 and 8.2 above) for expedited reporting purposes only.

Attribution of the AE:
Definite – The AE **is clearly related** to the study intervention.
Probable – The AE **is likely related** to the study intervention.
Possible – The AE **may be related** to the study intervention.
Unlikely – The AE **is doubtfully related** to the study intervention.
Unrelated – The AE **is clearly NOT related** to the study intervention.

10.3 DSMC SAE Reporting Requirements

The Data Safety Monitoring Committee (DSMC) is responsible for the data and safety monitoring of approved and activated AHWFBCCC investigator-initiated, interventional studies as outlined in the AHWFBCCC Data and Safety Monitoring Plan.

11.0 Reporting of Unanticipated Problems, Adverse Events or Deviations

The interventionist will monitor and note any adverse events experienced when meeting with participants (e.g., patients' expression of emotional distress, request to discontinue the session). The study team will only document adverse events volunteered during interactions with participants or data collection activities.

Any unanticipated problems involving risks to subjects or others and adverse events shall be promptly reported to the IRB, according to institutional policy. Reporting to the IRB is required regardless of the funding source, study sponsor, or whether the event involves an investigational or marketed drug, biologic or device. Reportable events are not limited to physical injury, but include psychological, economic and social harm. Reportable events may arise as a result of drugs, biological agents, devices, procedures or other interventions, or as a result of questionnaires, surveys, observations or other interactions with research subjects.

In the rare event that a participant reports severe depressive symptoms or suicidality during the course of the study to research staff, we will inform the participant's oncologist and/or other clinical staff regarding concern for depression and need for further evaluation. Referrals may also be made to the psychosocial support team, as appropriate.

All members of the research team are responsible for the appropriate reporting to the IRB and other applicable parties of unanticipated problems involving risk to subjects or others. The Principal Investigator, however, is ultimately responsible for ensuring the prompt reporting of unanticipated problems involving risk to subjects or others to the IRB. The Principal Investigator is also responsible for ensuring that all reported unanticipated risks to subjects and others which they receive are reviewed to determine whether the report represents a change in the risks and/or benefits to study participants, and whether any changes in the informed consent, protocol or other study-related documents are required.

Any unanticipated problems involving risks to subjects or others occurring at a site where the study has been approved by the WFUHS IRB (internal events) must be reported to the WFUHS IRB within 7 calendar days of the investigator or other members of the study team becoming aware of the event.

Any event, incident, experience, or outcome that alters the risk versus potential benefit of the research and as a result warrants a substantive change in the research protocol or informed consent process/document in order to insure the safety, rights or welfare of research subjects must be reported to the WFUHS IRB within 7 calendar days of the investigator or other members of the study team becoming aware of the event.

Appendix A – Subject Eligibility Checklist

IRB Protocol No. ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**WFBCCC Protocol No.** ONC-LUN-2403
Study Title: Toward an integrated approach to assessing and addressing follow-up care needs that will facilitate care transitions for cancer survivors: A pilot study	
Principal Investigator: Sarah Birken, PhD	

Inclusion Criteria (as outlined in study protocol)	**Criteria is met**	**Criteria is NOT met**	**Source Used to Confirm * (Please document dates and lab results)**
Patients must have histologically or cytologically confirmed stage I-IV lung cancer	☐	☐	
Ability to understand and the willingness to sign an IRB-approved informed consent document	☐	☐	
≥18 years of age	☐	☐	
Within two years of lung cancer diagnosis	☐	☐	
Able to understand, read and write English	☐	☐	
Exclusion Criteria (as outlined in study protocol)	**Criteria NOT present**	**Criteria is present**	**Source Used to Confirm * (Please document dates and lab results)**
	☐	☐	

This subject is ☐ eligible / ☐ ineligible for participation in this study.

OnCore Assigned PID: ___ ___ ___ ___ ___ ___ ___ ___

Signature of research professional confirming eligibility: _____
Date: ___ ___ / ___ ___ / ___ ___

Signature of Principal Investigator**: _____
Date: ___ ___ / ___ ___ / ___ ___

* Examples of source documents include clinic note, pathology report, laboratory results, etc. When listing the source, specifically state which document in the medical record was used to assess eligibility. Also include the date on the document. Example: “Pathology report, 01/01/14” or “Clinic note, 01/01/14”

**Principal Investigator signature can be obtained following registration if needed

Appendix B – Protocol Registration Form

☐ NC002 – WF Main Campus

☐ NC145 – High Point – Hayworth Cancer Center

☐ NC272 – Mount Airy

☐ NC295 – Wilkes

☐ Other: _____

☐ NC273 – Elkin

☐ NC274 – Lexington

☐ NC275 – Clemmons

☐ NC298 - Statesville

Sex Assigned at Birth: ☐ Female ☐ Male

Registration Date: ___ ___ / ___ ___ / ___ ___

Registered By: _____

Protocol Number _____

Date Consent Signed:

(Consent must be signed prior to registration) ___ ___ / ___ ___ / ___ ___

On Arm Date: ___ ___ / ___ ___ / ___ ___

Treatment Assignment/Arm: _____

Wiser Sequence No: _____

Patient: Last Name: _____ First Name: _____

MRN: ___ ___ ___ ___ ___ ___ ___ ___

DOB (mm/dd/yy): ___ ___ / ___ ___ / ___ ___

ZIPCODE: ___ ___ ___ ___ ___

Method of Payment: (Private; Medicare; Medicare + Private; Medicaid; Medicaid + Medicare; Military; Veteran Support; Self-Pay; None; Unknown; Other,

Specify)_____

Disease Site:_____

Example:C67.9 - Bladder, unspecified

Histology: _____

Date of Diagnosis: ___ ___ /___ ___/___ ___ ☐ Actual ☐ Approximate

INDUSTRY PID:

GROUP PID: (Alliance, ABTC, SWOG, ETC.): N/A

STEP NUMBER: (Alliance, SWOG, ETC.): N/A

ASSIGNED ARM: N/A

This protocol utilizes Reduced Review registration and eligibility will not performed by the registrar.

Appendix C - Race & Ethnicity Verification Form

Thank you so much for helping us to verify your race and ethnicity to ensure the quality of our information. As a brief reminder, the information you provide today will be kept confidential.

1. Are you:
   - ☐ Hispanic or Latino/a
   - ☐ Not Hispanic or Latino/a

2. What is your race? One or more categories may be selected.
   - ☐ White or Caucasian
   - ☐ Black or African American
   - ☐ American Indian or Alaskan Native
   - ☐ Asian
   - ☐ Native Hawaiian or Other Pacific Islander
   - ☐ Other, Please Specify: _____

Internal use only:

Name: _____ MRN#: _____

Was the self-reported race and ethnicity of the participant verified at the time of consent?
☐ **Yes** ☐ **No**

Was a discrepancy found? ☐ **Yes** ☐ **No**
If yes, please provide what is currently indicated in the EMR:
Ethnicity: _____ Race: _____

Additional comments:
_____
_____
_____
_____

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