EXPANDING RURAL HEALTH CANCER CONTROL CAPACITY: FOCUS ON CANCER SURVIVORSHIP

STUDY PROTOCOL

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TABLE OF CONTENTS

STUDY PROTOCOL

1. OVERVIEW AND SPECIFIC AIMS

Through this pilot study, we will test an innovative approach to implement survivorship care planning at three sites in the Baptist Memorial Health Care Corporation (BMHC) located in or adjacent to rural counties in our catchment area. The pilot data will inform a subsequent multi-site Hybrid Type 3 Implementation-Effectiveness study that will assess both implementation and clinical effectiveness outcomes. The overall goal of this study is to improve long term health outcomes for underserved rural cancer survivors by building capacity of rural health systems, in collaboration with an NCI-designated comprehensive cancer center, to deliver risk-adapted guideline-based care focused on the unique needs of cancer survivors. To accomplish this goal, we will address two specific aims.

1. Pilot test the implementation of guideline-based survivorship care planning in a rural setting using patient navigation plus telehealth among underserved rural cancer survivors. We will collect feasibility data on patient recruitment rates and the ability to measure clinical effectiveness outcomes using the electronic health record and patient reports (survivor adherence to recommended disease surveillance, health assessment and cancer prevention/early detection practices).
2. Identify the facilitators and barriers to future larger scale implementation of guideline-based survivorship care planning in rural settings to optimize the implementation strategies. Through a mixed methods approach, we will address implementation research questions focused on "real world" implementation of the guideline-based intervention in rural areas, including barriers/facilitators and translation to other rural settings. This will allow us to optimize the implementation strategies that will be further evaluated in the future large-scale implementation trial.

2. BACKGROUND AND STUDY RATIONALE

For those living in rural areas who are successfully treated for cancer, little is known on how to best address the potential long-term health burden, including need and accessibility of cancer and control services[1-2]. Research is required on how to best implement guideline-based, locally accessible survivorship care to rural cancer survivors. Leveraging the expertise of an NCI-designated comprehensive cancer center with a large rural population [such as the Vanderbilt-Ingram Cancer Center (VICC)] can help build capacity to attain this goal. Through this study, we will improve our understanding of the needs of cancer survivors in rural communities in the VICC catchment area and optimize promising implementation strategies that could help rural healthcare facilities overcome challenges to delivering guideline-based survivorship care planning and delivery. Further, we will enhance our capacity to bring cancer prevention and control research, education and services to this population.

3. RESEARCH DESIGN AND METHODS

3.1 IRB Approval

Each clinical site must obtain IRB approval for this protocol and submit IRB approval and supporting documentation to the Coordinating Center before they can be approved to enroll patients. Centers will use the sIRB mechanism with Vanderbilt-Ingram Cancer Center (VICC) as the coordinating center.

3.2. Study Population

This pilot study population will include the following individuals selected from healthcare sites within the BMHC, serving a rural population:

a. Post-treatment cancer patients
b. Oncology providers
c. BMHC healthcare staff

3.3. Patient Eligibility Criteria

1. Cancer patient at least 18 years of age at time of cancer therapy and English-speaking with the ability to provide informed consent
2. Received treatment for Stage 0 – III cancer with curative intent
3. Completed cancer therapy within the previous 12 months (i.e., 12 months prior to consenting) and in complete remission

3.4. Research Procedures

The pilot study will use a mixed methods approach to assess the implementation of guideline-based survivorship care planning in a rural setting. Both quantitative (QUAN) and qualitative (QUAL) data will be collected in a sequential order through surveys and interviews.

Patient Recruitment, Enrollment, & Data Collection

Study Sites:

- Cancer clinics within the Baptist Memorial Health Care Corporation

The VICC study team will communicate with designated BMHC staff at the study sites to identify cancer patients eligible for this study and their treating BMHC oncology provider. The VICC study team will contact the identified oncology provider(s) or staff to offer information about the patient intervention, which includes (1) local patient navigation and (2) telehealth-facilitated delivery of survivorship care, and request that provider gather interest from their patient in participating. If the patient expresses interest in participating, a participating BMHC oncology provider and/or research staff will talk to the patient further about the study. The VICC study team may contact the patient by mail, email, phone, or in person to provide additional information about the study, if needed. If the patient is willing to participate, BMHC research staff will confirm the patient's eligibility based on the aforementioned criteria, then prompt them to complete the study's required informed consent form either on paper or online through REDCap.

Consented patient participants will then be asked to complete a Patient Demographic Survey and the National Comprehensive Cancer Network (NCCN) Distress Thermometer Survey[5] online through REDCap, on paper, or over the phone.

Survivorship Patient Navigation Intervention: Participants will then be assigned to a patient navigator to assist the participant either in person, by email, or over the phone with navigation of the fragmented healthcare system and help survivors find and utilize resources and services, available locally or through VICC, if not locally available, to meet identified follow-up recommendations.

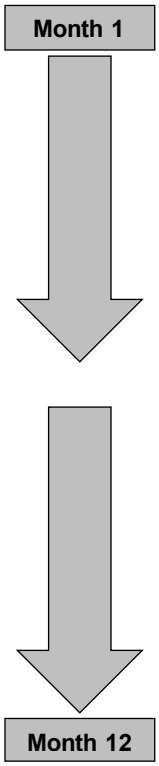
Telehealth Survivorship Visit Intervention: The designated patient navigator will schedule for the participant, at their convenience, a telehealth survivorship visit with a REACH nurse practitioner and a research nurse who will review a survivorship care plan (SCP) with the participant based on their medical history and review of medical records. REACH is the cancer survivorship program

offered through VICC. Following the telehealth visit, the SCP will be finalized, and a copy shared digitally (or in print, if needed) with the participant, the treating oncology provider(s), the participant's primary care provider, and other care providers requested by the participant. The REACH nurse practitioner and patient navigator will work together to advise and assist the participant and their care team in recommended follow-up, including services available locally or through VICC via telehealth. The patient navigator will also assist the participant with follow-up logistics.

Three months post the aforementioned telehealth survivorship visit, participants will be asked to complete the NCCN Distress Thermometer Survey[5] and the Patient Post-Intervention REACH Satisfaction Survey to rate the quality and salience of the survivorship care planning to their specific needs and their overall satisfaction with the program. The Patient Post-Intervention REACH Satisfaction Survey will assess perceived utility, benefit, accessibility importance and favorability. Qualitative (open-ended) items will ask for feedback on aspects of the program they liked most, how it could be improved, and any challenges with receiving survivorship care via telehealth. All surveys may be completed either on paper, online through REDCap, or over the phone.

A sub-group of up to 20 participants will be asked to complete interviews and/or focus groups after completion of the telehealth survivorship visit. Interviews and/or focus groups will be audio recorded, using a semi-structured interview guide. Participants who complete an interview and/or focus group will receive a $25 gift card in compensation for their time. The interview questions are adapted from the existing CFIR Interview Guide, covering the selected constructs appropriate for the population. As Survivorship Care Plans (SCPs) do not appear to improve outcomes in and of themselves, we will focus on what factors positively or negatively affected recommended follow-up.

Patient Timeline



Timepoint	Action
Recruitment	Recruited through a referral by their oncologist, then study personnel will inform patient of study
Enrollment	Patient will sign required consent form. Patient Demographic Survey and NCCN Distress Thermometer Survey[5] will be administered
Telehealth & Survivorship Navigation Program	Participation in intervention
Post-telehealth intervention	Patient Post-Intervention REACH Satisfaction Survey and NCCN Distress Thermometer Survey[5] administered 3 months after intervention
End of Study	Participation in qualitative interviews and/or focus groups

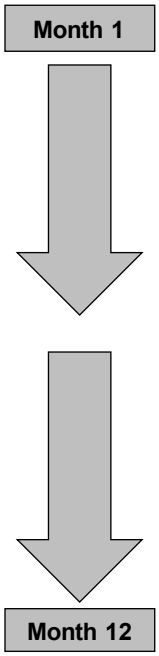
BMHC Oncology Providers & Staff Data Collection

BMHC oncology providers or staff who have referred a consented patient participant to the study will be asked to review an information sheet and consent to completing a Provider Demographic Survey to collect basic demographic information online through REDCap, on paper, or over the phone.

Three months after the patient participant referred by the oncologist or staff member has completed the telehealth survivorship visit, the provider or staff member will be asked to complete the Provider Post-Intervention REACH Satisfaction Survey online through REDCap, on paper, or over the phone to assess perceived utility, benefit, accessibility importance and favorability. Qualitative (open-ended) items will ask for feedback on aspects of the program they liked most, how it could be improved, and any challenges with receiving survivorship care via telehealth.

A sub-group of six oncology providers and 12 staff will be asked to complete key informant interviews and/or focus groups. Providers or staff who complete an interview and/or focus group will receive a $25 gift card in compensation for their time. The interview questions are adapted from the existing CFIR Interview Guide, covering the selected constructs appropriate for the population. As Survivorship Care Plans (SCPs) do not appear to improve outcomes in and of themselves, we focus on what factors positively or negatively affected recommended follow-up.

BMHC Provider/Staff Timeline



Timepoint	Action
Recruitment	Study personnel will reach out to providers/staff to inform them of the study. If interested, the provider/staff will inform their patient
Enrollment	Provider/staff will review a required information sheet. Provider Demographic Survey administered
Telehealth & Survivorship Navigation Program	N/A
Post-telehealth intervention	Provider Post-Intervention REACH Satisfaction Survey administered
End of Study	Participation in qualitative interviews and/or focus groups

3.5 Study Timeline

Timepoint	Action

Notification of Grant Award	Study Coordinator and patient navigators will be hired
	Three sites within BMHC will be confirmed
Months 1-3	Navigators may receive VICC's existing lay patient navigation training and may participate in the GWCI "Oncology Patient Navigator Training: The Fundamentals"
Months 4-12	Survivorship Care Plans will be created and delivered via telehealth by REACH nurse practitioner and a research nurse
	Patient navigator will assist patient with needs and identifying local resources
	Surveys will be administered, and data will be collected and evaluated from them
	Assessment of barriers and facilitators will take pace

3.6. Process Evaluation and Analysis

Process Evaluation Data: Implementation penetration will be assessed as a ratio of number of patients who participate in survivorship care planning divided by total number of potential participants approached at each recruitment site. To address implementation fidelity, we will examine adherence of navigators and nurses to facilitate the process following the protocol set forth using an adapted Fidelity Checklist[3]. Participant responsiveness will be measured as satisfaction with the survivorship care planning from the post surveys.

Data Analysis. We will use a connecting process to combine both types of data through complementarity, using the qualitative data to explain the quantitative outcomes in more detail. Descriptive analyses will be used for the quantitative data. Qualitative software will be used to code the interview transcripts using the CFIR Codebook Template[4]. We will use thematic analysis method to identify and analyze commonly recurring themes.

Feasibility data on patient recruitment rates and the ability to successfully measure relevant clinical effectiveness outcomes will be collected. Through electronic health records and participant surveys, we will retrospectively review the following clinical effectiveness outcomes: survivor adherence to recommendations made as part of survivorship planning, including disease specific follow-up, cancer screening and risk-based health promotion.

4. RESEARCH TEAM

Debra Friedman, MD, MS, Principal Investigator

Co-investigators:

Tuya Pal, MD

Research Staff:

Claudia Barajas

Denise Martinez

Jacob McArthy, MS

Kelsey Minix, MPH

Emma Schremp, MS

Ann Tezak, MA, MPH

Anne Washburn, MPH

5. POTENTIAL RISKS

There is a slight risk of accidental release of confidential information. The study team attempts to minimize this risk by limiting access to PHI. All confidential records that could identify subjects will be protected, respecting the privacy and confidentiality rules in accordance with the IRB's regulatory requirements. The study team will perform the study according to good clinical practices.

6. POTENTIAL BENEFITS

There are no direct benefits to participants from participating in this study. However, the benefits to science and humankind that may result from this study are that the data obtained may inform therapy for patients in the future and surveillance and secondary prevention interventions to avoid adverse long-term outcomes for current long-term survivors.

7. REPORTING OF ADVERSE EVENTS OR UNANTICIPATED PROBLEMS INVOLVING RISK TO PARTICIPANTS OR OTHERS

No adverse events are anticipated for this study. Although no adverse events are anticipated for this study, the PI will report any adverse events to the IRB immediately.

8. STUDY WITHDRAWAL/DISCONTINUATION

Participants are free to stop participating at any time without penalty. Participants may also choose not to answer any questions that make them feel uncomfortable.

9. PRIVACY/CONFIDENTIALITY ISSUES

Telehealth and Survivorship Patient Navigation: Telehealth visit conducted via HIPPA compliant software.

Surveys: Only study personnel will have access to the information collected on paper surveys. Questionnaires completed online or collected over the phone will be directly entered into the secure, password-protected REDCap database for the respective participant's record. ID numbers will be assigned to surveys with access only to study personnel.

Qualitative Interviews: The digital audio recordings will be stored on password protected computers until they are transcribed, with access only available to study personnel.

10. FOLLOW-UP AND RECORD RETENTION

Surveys: ID numbers will be assigned to surveys with access only to study personnel. Online data will be stored on a secure REDCap database.

Qualitative Interviews: The digital audio recordings will be stored on password protected computers until they are transcribed, with access only available to study personnel. After the information is transcribed, the recordings will be deleted.

11. REFERENCES

1. American Cancer Society. Cancer Facts & Figures 2019. Atlanta: American Cancer Society; 2019
2. Aziz, NM, Rowland, JH, Cancer survivorship research among ethnic minority and medically underserved groups. Oncol Nurs Forum, 2002. 29(5):789-801.
3. Breitenstein SM, Fogg L, Garvey C, Hill C, Resnick B, Gross D. Measuring implementation fidelity in a community-based parenting intervention. Nursing Research. 2010;59:158-65
4. Consolidated Framework for Implementation Research. Center for Clinical Management Research. 2018; 2018
5. National Comprehensive Cancer Network. Distress Thermometer Scale. September 7, 2018. http://www.nccn.org/professionals/physician_gls/pdf/distress.pdf.