A pilot study to examine feasibility of a patient directed tool to assess heart health among endometrial cancer survivors

Wake Forest Baptist Comprehensive [redacted] Center (WFBCCC)
WFBCCC 99123

ClinicalTrials.gov: NCT05796518

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Participating Institution(s): Wake Forest Baptist Comprehensive Cancer Center

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Confidential

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SCHEMA

Study Population: Endometrial cancer survivors presenting to WFBCCC for post-treatment surveillance visit.

Intervention: Implementation of the PREVENT cardiovascular health (CVH) assessment tool and provider education sessions

Data Collection from Survivors: Pre-visit, post-visit and 1 months - demographics, referrals to health services (including primary care and cardiology), CVH discussions, cardiovascular risk factor data

Primary Endpoint: Proportion of patients who consent to the study and complete the web-based heart health assessment.

1.0 Introduction and Background

Endometrial cancer is the most common gynecologic malignancy, and with approximately two-thirds of cases being diagnosed at an early stage it carries an excellent 5-year overall survival of approximately 95%.[1] Survivors of endometrial cancer are more likely to die of their comorbidities than their cancer, and cardiovascular disease (CVD) is not only the leading cause of death in the United States but has also been found to be the leading cause of death among endometrial cancer patients.[2-4] This is likely due to the multiple overlapping risk factors for endometrial cancer and CVD including obesity and metabolic syndrome, elevating the importance of addressing cardiovascular (CV) health in routine survivorship care.[5,6] Treatment of endometrial cancer adds to this risk, with a decrease in physical activity and subsequent weight gain during the post-operative period and concurrently undergoing adjuvant treatment with chemotherapy or radiation.

The National Comprehensive Cancer Network (NCCN) recommends assessment of CVD risk in their endometrial cancer survivorship guidelines.[9] This is reinforced in the primary gynecologic oncology literature, with CVD risk assessment in patients with endometrial cancer suggested to be implemented as early in survivorship care as possible.[2] However, implementing this guideline in routine oncology practice may be challenging. Using survey data of over 1500 patients with breast, prostate, colorectal and gynecologic cancers, Weaver at al. found that one in three survivors with at least one CV risk factor reported no discussion of health promotion with their oncologic provider.[10] Similarly, in a survey of 700 patients with a cancer diagnosis, Nicolaije et al. found that 35% of patient responded that they were minimally informed on how to improve their health, with 42% responding that they were completely uninformed on how to improve their health.[11] Ninety percent of oncologists in an electronic health record (EHR) tool pilot study (18 of 20) reported CV health discussions to be “somewhat” or “very” important; however, 58% “rarely” or “sometimes” discuss CV health with their patients.[12] As a result, oncologists make few referrals for CV care to primary care and cardiology for guideline-driven follow-up care.[10,13-15]

Primary care is a key partner for managing CV health among cancer survivors. We are not aware of any studies specifically looking at primary care practitioner (PCP) utilization by endometrial cancer survivors, however, studies have shown that up to 20% of patients with a history of breast or colon cancer did not see a PCP within the first year of survivorship.[7,8] Unsurprisingly, these patients were less likely to get preventative care and have chronic and general health issues managed than those who saw a PCP in addition to an oncology provider. Data from the original Automated Heart Health Assessment (AH-HA) team and others show that survivors want to have preventative discussions with their oncologists.[16] Although some oncology providers are hesitant to address obesity and exercise in cancer survivors, exercise recommendations by providers increase cancer survivors’ physical activity by up to 30 minutes per week.[17-19] Behavioral interventions for weight loss, exercise, diet, and smoking cessation, even if brief, can be successful in improving CV health among cancer survivors.[20-25] For example, the odds of abstinence from smoking at 6 months increased 66% with provider lifestyle advice.[25]

Web-based cardiovascular health assessment tools may play an important role in successful guideline implementation. The AH-HA tool, currently being tested in a large multi-site trial, is a provider facing EHR-embedded CV health assessment tool that renders a visual, interactive display of CVH risk factors, automatically populated from the EHR.[26] However, EHR integrated tools may require substantial time and cost for successful integration. A similar tool, named PREVENT, was developed by co-investigators on the proposed study using the American Heart Association (AHA) Simple 7 criteria for adolescent and young adult cancer patients, but is a web based, patient facing tool. This tool provides a graphic representation of the validated overall CV health score based on the Simple 7 risk factors[27], and provides behavior change recommendations to improve CV health. Provider and patient facing tools may offer implementation options to oncology clinics or be used as complementary strategies.

In this study, we will pilot an adapted version of the PREVENT tool for endometrial cancer survivors. This study will focus on the feasibility of using the PREVENT tool within routine follow-up care for endometrial cancer.

2.0 Objectives

2.1 Primary Objective

The primary objective of this *pilot* study is to assess the feasibility of enrolling and completing the heart health assessment among endometrial cancer patients scheduled for routine follow-up care.

2.2 Secondary Objectives

2.2.1 To assess patient satisfaction with the tool.

2.2.2 To identify the proportion of patients with non-ideal cardiovascular health scores who report initiating discussions regarding cardiovascular health during their routine oncology appointment.

3.0 Study Population

Endometrial cancer survivors presenting to WFBCCC for post-treatment surveillance visit.

3.1 Inclusion Criteria

3.1.1 Scheduled for a routine surveillance visit for pathologically confirmed stages I-IV endometrial cancer

3.1.2 ≥ 3 months post-potentially curative cancer treatment

3.1.3 Patients must be at least 18 years of age

3.1.4 Have a working email address

3.1.5 Comfortable reading medical information in English, as per self-report

3.2 Exclusion Criteria

3.2.1 Currently receiving treatment (e.g. radiation, chemotherapy, immunological treatments for endometrial cancer)
3.2.2 Have a history of endometrial cancer recurrence
3.2.3 Enrolled in hospice care or documentation of life expectancy < 6 months

3.3 Inclusion of Women and minorities

3.3.1 Women of all races and ethnicity who meet the above-described eligibility criteria are eligible for this trial. All of the participants will be women.

Minority Estimates: Similar to the national population data for cancer survivors and the demographics of the cancer patient population at the CCCWFU, non-Hispanic whites are expected to comprise the majority of our sample. Based on our cancer center data, we expect approximately 2% of included participants to be Hispanic/Latino (N=1). The breakdown of racial categories is expected to be as follows: 14% Black or African American (N=5), and 84% White (N=35), and 2% more than one race (N=1).

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.

4.0 Methods

4.1 Registration Procedures

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

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

1.0 Complete the Eligibility Checklist (Appendix A)
2.0 Complete the Protocol Registration Form (Appendix B)
3.0 Alert the Cancer Center registrar by phone, *and then* send the Informed Consent Form, Eligibility Checklist and Protocol Registration Form to the registrar, either by fax or e-mail.

Contact Information:
Protocol Registrar PHONE [redacted]
Protocol Registrar FAX [redacted]
Protocol Registrar E-MAIL [redacted]

*Protocol Registration is open from 8:30 AM - 4:00 PM, Monday-Friday.

4.0 Fax/e-mail ALL eligibility source documents with registration. Patients **will not** be registered without all required supporting documents.

Note: If labs were performed at an outside institution, provide a printout of the results. Ensure that the most recent lab values are sent.

To complete the registration process, the Registrar will:

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

4.2 Experimental or Data Collection Methods

Data will be collected through patient surveys via REDCap, and the PREVENT tool, as well as via medical chart abstraction for lab values and vital signs.

4.2.1 EHR data extraction
Patient demographics (e.g., sex, date of birth, race/ethnicity) and the most recent risk factors for CVH (height, weight, fasting blood glucose, total cholesterol, blood pressure, smoking status) will be extracted at baseline (prior to clinic visit). Available EHR data will be uploaded into PREVENT prior to the clinic visit but may be updated within the PREVENT tool at the time of the clinic visit if updated values are attained. We acknowledge that not all patients will have updated information for CVH risk factors (fasting blood glucose, Hemoglobin A1c and total cholesterol). This pilot study is intended to determine what data are commonly available for a future study. We expect that height and weight will be the most commonly available data point.

4.2.2 Survey data

The pre-assessment survey will be sent electronically using REDCap to give the patient the option of completing the survey prior to the clinic visit. Alternatively, the patient may complete the questionnaire while in the waiting room at the clinic. The post-assessment survey will also be sent electronically using REDCap.

4.3 Study-Related Activities

	Screening[a]	Pre-Visit Assessment[a,b]	During Visit	Post-Visit Assessment[c] (+ 14 Days)	1 Month Post-Visit[f] (+/- 15 Days)
Eligibility	X				
Screen Failure Form	X				
Informed Consent		X			
Health Assessment		X		X	
Health Visit Information		X			
Health Knowledge Assessment		X		X	
Demographic & Health Behaviors		X			
Referral Assessment				X	
Tool Use			X[e]		
Tool Assessment				X	
Medical Record Data		X[d]			X

a) Occurs pre-registration.
b) Pre-visit assessment may be completed online via REDCap or on the day of study visit.
c) Post-visit assessment should be completed at the end of study visit. If post-visit assessment cannot be completed at the end of the study visit, the assessment may be completed online by the patient via REDCap, ideally within 48 hours of study visit.
d) Most recent patient vitals as well as fasting blood glucose, Hemoglobin A1c and total cholesterol will be extracted provided test results are within five years. Data extraction may be completed prior to visit or on day of study visit.
e) This data will be collected directly in the tool and will not need to be entered in REDCap by staff.
f) This is chart abstraction by staff, using the HER and data extraction form. There is no additional patient visit associated with this activity.

Basic Study Overview

This will be a single arm pilot study conducted at a single academic medical center (WFBCCC). We will identify, recruit, and consent endometrial cancer patients scheduled for a routine surveillance visit with a gynecologic

oncology provider. Patients will consent to the study and complete a brief questionnaire electronically prior to presenting for their office visit. Once they have been roomed in the office, a research team member will assist them in the use of the PREVENT tool, yielding a cardiovascular health score. Questions regarding the score will be directed towards their oncologic provider. They will then complete a brief questionnaire immediately after the visit. Chart review will be conducted 3 months after the visit.

Consent and Survey Administration: We will request a waiver of signed informed consent for the study (see Protection of Human Subjects). Potential participants identified from cancer center appointment schedules or referred by clinicians and navigators will be recruited by patient portal, phone, or in-person to complete brief web-based surveys before and after their regularly scheduled medical appointment. A record of screening failures will be captured Survey participants will receive a $10 gift card.

Pre-Assessment Questionnaire: Prior to exposure to the PREVENT tool, we will ask 8 questions about CVH knowledge and perceived importance and appropriateness of heart health discussions during oncology care.

PREVENT Tool Interaction: While the patient is having their regularly scheduled medical appointment, the study coordinator will review their medical chart for cardiovascular risk information (weight, height, smoking status, blood pressure, total cholesterol, and hemoglobin A1c or fasting glucose). The most recent data will be entered in the PREVENT tool for the patient. We will help survivors access a patient-facing version of the PREVENT tool using a personal device or a study tablet computer. Survivors will use a personal email address to log-in to the patient-facing web application and will receive a welcome email after configuring their PREVENT profile. Patients will have the opportunity to review and update any of their cardiovascular risk information, as well as read information about cardiovascular health. The research coordinator will assist survivors in using the tool if requested.

Post-Assessment Questionnaires: Following survivor interaction with the PREVENT tool, survivors will complete:

- The same eight pre-assessment questionnaire along with three additional questions.

- We will additionally ask 5 questions regarding use of the PREVENT tool.

Collection of Post-Intervention Clinical Follow Up: Data will be collected about referrals, labs and new medications that occur during the 3-month period after their use of the study tool.

5.0 Outcome Measures

5.1 Primary Outcome

Proportion of patients who consent to the study and complete the web-based heart health assessment.

5.2 Secondary Outcomes

5.2.1 Secondary objective 2.2.1, patient satisfaction identified through post-visit survey with a 5-point Likert scale (strongly agree to strongly disagree) regarding liking the tool, helpfulness, ease of understanding and desire to use this tool with their oncologist.

5.2.2 Secondary objective 2.2.2, proportion of patients who report initiating discussions regarding cardiovascular health, identified through post-visit survey.

6.0 Analytic Plan

6.1 Sample Size and Power

This pilot study has an accrual goal of 42 endometrial cancer survivors. This study focuses on the feasibility of implementing the PREVENT tool to promote discussion of cardiovascular health risks between providers and cancer survivors. Feasibility will be defined from the proportion of patients who complete the web-based assessment. A sample size of 42 total participants will have 83% power to detect a hypothesized participation rate of 80% or more with an unacceptable participation rate considered 60% or less. This assumes a conservative 10% dropout of participants prior to the time of visit, with a one-sided alpha=0.05, and one-sample exact binomial test. Assuming 37 survivors complete the assessment, we will be able to estimate participation within +/- 17% using exact 95% binomial confidence intervals. A sample size of 37 survivors would allow for reasonable estimates of SDs that could be used for future studies.

6.2 Analysis of Primary Outcome

For our primary objective, analyses will be largely descriptive (using means, medians, frequencies etc.).

6.3 Analysis of Secondary Outcomes

For secondary objective 2.2.1, patient satisfaction with the tool, one-sample t-tests will be used to test whether the average response to each question is greater than 3.5 (with three denoting a neutral response). Wilcoxon signed rank tests will be used to compare cancer survivors' knowledge regarding their cardiovascular health risk factors and perceived importance of cancer

and heart disease before and after using the CV risk visualization tool. Categorical comparisons will be evaluated with Fisher's Exact test.

For secondary objective 2.2.2, analyses will be largely descriptive (using means, medians, frequencies etc.).

6.4 Accrual Rate

Accrual is expected to be 10 patients per month, based on an estimated 20 endometrial cancer survivors seen by the gynecologic oncology department for surveillance in the average month.

6.5 Length of Study

Targeted accrual should be met in approximately 6 months. A maximum of 42 patients will be enrolled on this trial.

7.0 Data Management

Data Collection Form	Data Storage Location
Informed Consent Document	EPIC
Subject Eligibility Checklist	WISER/OnCore
Protocol Registration Form	WISER/OnCore
Race & Ethnicity Form	WISER/OnCore
Screen Failure Form	REDCap
Pre-visit Baseline Survivor Survey	REDCap
Data entered into PREVENT	Google Firebase
Post-Baseline Survivor Survey	REDCap
Tool Assessment (v1.0)	REDCap
Gift Card Tracking Form	REDCap
Medical Record Extraction	REDCap
Off Treatment Form	WISER/OnCore
Off Study Form	WISER/OnCore
Withdrawal of Consent	WISER/OnCore
Survival Form	WISER/OnCore

This project will utilize REDCap Clinical Data Interoperability Services. This is a special feature for importing data into REDCap from WakeOne. It provides an adjudication process whereby REDCap users can approve all incoming data from WakeOne before it is officially saved in their REDCap project. REDCap Clinical Data Interoperability Services can only be enabled by a REDCap administrator who serves as an honest broker to PHI. REDCap's Clinical Data Interoperability Services can only be accessed by users with valid WakeOne credentials. Using the Clinical Data Interoperability Service requires using the Medical Record Number (MRN) as a key to automatically gather demographics and laboratory data and reduces data entry errors.

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 two years after closure of the study, 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.

Data will be stored on a secure information technology-maintained computing infrastructure behind the WFBH firewall, which has been certified to store protected health information. Data from the PREVENT tool will also be stored on a secure information technology-maintained platform (Google Firebase) that complies with HIPPA standards. We will take consistent measures to protect the confidentiality of these data. When the data are collected and ready for analysis, the dataset will be downloaded by Dr. DeMari and used only for the purposes identified in these analyses. Only approved members of the research team will have access to these data.

10.0 Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

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Appendix A – Subject Eligibility Checklist

IRB Protocol No. ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**WFBCCC Protocol No** ___ ___ ___ ___ ___
Study Title: A pilot study to examine feasibility of a patient directed tool to assess heart health among endometrial cancer survivors	
Principal Investigator: Kathryn E. Weaver, PhD, MPH	

Inclusion Criteria (as outlined in study protocol)	**Criteria is met**	**Criteria is NOT met**	**Source Used to Confirm * (Please document dates and lab results)**
Scheduled for a routine surveillance visit for endometrial cancer	☐	☐	
≥ 3 months post-potentially curative cancer treatment	☐	☐	
Age >/= 18 years	☐	☐	
Have a working email address	☐	☐	
Comfortable reading medical information in English, as per self report	☐	☐	
Exclusion Criteria (as outlined in study protocol)	**Criteria NOT present**	**Criteria is present**	**Source Used to Confirm * (Please document dates and lab results)**
Currently receiving treatment (e.g. radiation, chemotherapy, immunological treatments for endometrial cancer)	☐	☐	
Have a history of endometrial cancer recurrence	☐	☐	
Enrolled in hospice care or documentation of life expectancy < 6 months	☐	☐	

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

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

Signature of research professional confirming eligibility:_____

Date: ___ ___/___ ___/___ ___

Signature of Treating Physician**: _____

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

DEMOGRAPHICS

Patient: Last Name: _____ First Name: _____

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

ZIPCODE: ___ ___ ___ ___ ___

SEX: ☐ Male ☐ Female

Height: ___ ___.___ inches Weight: ___ ___ ___.___lbs.(actual)

Surface Area: ___ ___.___m^2

Primary Diagnosis: _____

Date of Diagnosis: ___ ___ /___ ___/___ ___

Performance Status: ___ ☐ ECOG

PROTOCOL INFORMATION

Date of Registration: ___ ___ / ___ ___ / ___ ___

MD Name (last) : _____

PID # (to be assigned by OnCore): ___ ___ ___ ___ ___ ___ ___ ___

Protocol Registrar can be contact by calling [redacted] between 8:30 AM and 4:00 PM, Monday – Friday.

Completed Eligibility Checklist and Protocol Registration Form must be hand delivered, faxed or e-mailed to the registrar at [redacted].

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:

_____
_____
_____
_____