A Pilot Study to Examine Feasibility of a Patient Directed Tool to Assess Heart Health Among Endometrial Cancer Survivors
NCT05796518
IRB Approved Date: 7/11/23

Department of Public Health Sciences/ Social Sciences & Health Policy

A PILOT STUDY TO EXAMINE FEASIBILITY OF A PATIENT DIRECTED TOOL TO ASSESS HEART HEALTH AMONG ENDOMETRIAL CANCER SURVIVORS

Informed Consent Form to Participate in Research
Kathryn Weaver, PhD, Principal Investigator

SUMMARY

You are invited to be in a research study. The purpose of this research is to see if a heart health assessment tool can be used during regularly scheduled follow-up visits. You are invited to be in this cancer survivor research study because you have completed treatment for endometrial cancer. Your participation in this research will involve one visit and the study will last about 3 months.

Participation in this study will involve completing two surveys and a web-based heart health assessment. All research studies involve some risks. A risk to this study that you should be aware of is that some of the surveys may increase feelings you may be having about your health or conditions. There also is a risk of breach of confidentiality.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include not participating in the study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator, Dr. Kathryn Weaver, at [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies help scientist learn new information that may help other people in the future. You are being asked to be in this study because you have completed treatment for endometrial cancer. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

Why Is This Study Being Done?

We are conducting this study to find out more about what your heart health means to you, and how your healthcare providers can best help you to manage your heart health. We will ask you to view an electronic tool designed to promote heart health awareness and help you to manage your heart health outside of the clinic. This study will provide important information to help us develop future programs that improve cancer patient's heart health after they complete their treatment.

How Many People Will Take Part in the Study?

42 cancer survivors at a single research site will take part in this study.

What Is Involved in the Study?

To participate in this study, you will meet with a study coordinator for approximately 10 minutes before and after your regularly scheduled oncology appointment. You will access a heart health information visualization tool online using a personal device or a study tablet computer using your e-mail address to log-in. We are asking your permission to look at your lab results specifically related to your cardiovascular health (e.g. blood pressure, cholesterol) in order to personalize the heart health tool for you. You will complete a brief survey before and after you use the tool.

How Long Will I Be in the Study?

The total time required to complete the surveys is approximately 10 minutes. On the surveys, you will be asked questions regarding your health and questions about if the tool was useful and easy to use. You can stop participating at any time.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the study include the following:

Minimal Risk	The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.
Confidentiality and privacy	Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.
Interview questions related to your heart health	As part of this study, you will be asked questions about your heart health. Some of these questions may be upsetting.

There also may be other risks that we cannot predict. You should tell the research staff about all

the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks to your health.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may receive a benefit from learning more about your current heart health and the steps that you may take to improve it. In addition, the information we gain will benefit cancer patients in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

Costs for your regular medical care, which are not related to this study, will be your own responsibility. The cost of your regularly scheduled oncology appointment will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

EMAIL COMMUNICATION. By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

If you agree to participate in the study, we will email you a brief survey before, and possibly after, your regularly scheduled oncology appointment. There may be monthly email reminders from the heart health tool to assess your progress, which you may opt out of at any time.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive a $10 gift card after you complete the post-visit survey to thank you for your time.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest School of Medicine. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** email addresses for participants, first name, last name, date of birth, medical record number. Your medical records will be reviewed in order to track your follow up visits.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which are identify you unless we have your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Kathryn Weaver that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Kathryn Weaver, PhD
Department of Social Sciences & Health Policy
Division of Public Health Sciences
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the

study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because new information becomes available or because the entire study has been stopped. Information that identifies you may be removed from the data that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study team by phone [redacted] or email [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this consent form.