Informed Consent Form Cover Page for ClinicalTrials.Gov Record

Official Study Title:

Improving Well-Being for Breast Cancer Patients Taking Adjuvant Endocrine Therapy

Brief Title:

Improving Well-Being for Breast Cancer Patients

NCT #: NCT02707471

Duke University Health System (DUHS) Protocol #: Pro00068595

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Document Name/Consent Type: Main Consent

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Improving Well-Being for Breast Cancer Patients

CONCISE SUMMARY

The purpose of this research study is to evaluate two different programs to help improve well-being among women taking a medication to reduce the risk of breast cancer coming back. Participants will complete an in-person baseline assessment and four follow-up assessments. Each of these in-person assessments will include a pill count, exercise testing, and the completion of surveys. At the end of the baseline assessment, participants will be randomized (like the flip of a coin) to receive a self-management intervention focused on coping with symptoms or a general health education intervention that focuses on improving overall health. Participants in either program will complete 10 phone sessions over the course of six months with a study nurse. During the baseline assessment, participants will also receive a special pill bottle to use for the breast cancer medication for 18 months. Each time the smart pill bottle is opened, it records the date and time and will send out a cellular signal. The total study duration is about 18 months.

There are minimal risks associated with this study. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you have been prescribed a medication to reduce your risk of breast cancer coming back. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Cancer Institute will sponsor this study. Portions of Dr. Rebecca Shelby's and her research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, you will not have a different medical doctor. Your regular doctor will continue to be your doctor throughout the time that you are in the study. A member of the study team may be in contact with your doctor throughout the time you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to evaluate two different programs to help improve well-being among women taking medication to reduce the risk of breast cancer coming back. One program focuses on strategies for coping with symptoms and improving well-being. The other program focuses on healthy lifestyle information and improving overall health.

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HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 480 people will take part in this research study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. Your medical record will be reviewed to obtain information about your breast cancer, treatments related to breast cancer, and other health conditions.

In this study, you will be randomly assigned (like the flip of a coin) to receive a self-management intervention focused on coping with symptoms or a general health education intervention that focuses on improving overall health. In these programs, you will be asked to complete ten 45 minute phone sessions with a study nurse and you will receive interactive voice response (IVR) phone calls each week. The phone sessions and IVR calls will take place over a six month period. The first three phone sessions will occur approximately once a week, the next four phone sessions will occur approximately every other week, and the last three sessions will occur approximately once per month. Phone sessions will be audio-recorded. Audio recordings will be available only to authorized study personnel as necessary to review the content of the sessions. All audio recordings will be destroyed at the end of the study.

All participants will complete an in person initial assessment and in person follow-up assessments 3, 6, 12, and 18 months later. During each assessment, you will answer questions about symptoms, emotions, stress, health, and health behaviors. The questionnaires will take approximately 45 to 50 minutes to complete. You will also be asked to complete a 6-minute walk test, a timed “get up and go” test, and a grip strength test during each of the 5 in-person assessments. You may choose not to complete the 6-minute walk test, and you will be encouraged to choose your own walking speed and to stop and rest throughout the 6 minutes, if needed.

You will be given an AdhereTech smart pill bottle to use for your breast cancer medication for the 18 months that you are in the study. Each time the smart pill bottle is opened, it records the date and time. The smart pill bottle sends out a cellular signal. Using the cellular network, the smart pill bottle will send information about bottle opening and medication refill status for review by the study team. You will also need to bring your breast cancer medication along with the most recent prescription bottle given to you by your pharmacist to each of the 5 in-person assessments, so study staff can count your pills.

HOW LONG WILL I BE IN THIS STUDY?

You will be in the study for approximately 18 months.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

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WHAT ARE THE RISKS OF THE STUDY?

There are minimal risks associated with this study. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. Some of the topics discussed during phone sessions may make you feel uncomfortable. Discussing your health or stressors associated with your health may be upsetting. You may choose to not discuss concerns you find upsetting. Also, you may stop your participation in this study at any time. There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Participation in this study will provide you with an opportunity to learn skills that can help you better manage symptoms or improve your overall health. We expect that the information learned from this study will benefit other patients with your condition in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

All audio recordings will be stored on an encrypted laptop and a DUHS server. Audio recordings will be available only to authorized study personnel as necessary for purposes of study and will only be identified by a study ID number. All audio recordings will be destroyed at the end of the study.

You will be assigned unique code numbers by the study and these numbers will be used for study service providers which include AdhereTech, Improved Patient Outcomes, and IVR Technology Group. AdhereTech is the service provider who makes the smart pill bottle used in this study. Adheretech will be given a study unique code number for you and will not have access to other direct personal identifiers. The smart pill bottle will transmit data about bottle opening, refill status, and bottle battery status and cellular connectivity to AdhereTech. This data will be stored on AdhereTech's servers. Study staff will retrieve this data from AdhereTech and will then store this data on a DUHS server. Improved Patient Outcomes is a service provider who will provide a customized software application for delivery of the study's intervention phone sessions and IVR calls. Improved Patient Outcomes uses a commercial IVR call provider, IVR Technology Group, to provide IVR calls. Study staff will give Improved Patient Outcomes a unique study code number for you, your name, your contact information including the phone number that you provide for IVR calls, demographic information, the best time to reach you, your AdhereTech smart pill bottle, and information about your experiences taking your breast cancer medication (i.e., if you indicate having a symptom or problem that makes it difficult to take your medication). IVR Technology group will have access to a unique study code number for you, your first name, your phone number, and your birth year. The limited personal information stated above will be disclosed by study staff to Improved Patient Outcomes and IVR Technology Group in order to

help customize the software and IVR calls that are used in this study. IVR Technology Group will have access to the IVR call content and will store this data in their network. IVR is not a completely secure or confidential means of communication and there is a chance that someone could hear the IVR calls.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the National Institutes of Health, Duke University Health System Institutional Review Board, Duke Cancer Institute & Clinical Trials Quality Assurance. If your research record is reviewed by this group, they may also need to review your entire medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to a total of $250 for your expenses related to your participation (parking, gas, and time). This reimbursement will consist of $50 for completing each of the study visits. If you choose to withdraw from the study, you only will receive compensation for the parts of the study that you completed.

WHAT ARE THE COSTS TO YOU?
There is no cost to you for your participation in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by

Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact Dr. Rebecca Shelby at (919) 416-3410 during regular business hours and page her at (919) 970-2033 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes except to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Rebecca Shelby in writing and let her know that you are withdrawing from the study. Her mailing address is 2400 Pratt St, 7th Floor, Room 7059, Durham, NC 27705. She may also ask you to complete the tests that would ordinarily occur when a person completes the study.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. Your doctor may decide to take you off this study if your condition gets worse or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent.

If you choose to withdraw from the study, your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical

record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Rebecca Shelby at (919) 416-3410 during regular business hours and page her at (919) 970-2033 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time