Consent to Participate in Research

Title of Research Study: *A Web-Based Tool to Improve Breast Cancer Survivorship*

Principal Investigator: ***Betina Yanez, PhD***

Supported By: This research is supported by the National Institutes of Health.

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is listed later on in this form. ***The purpose of this study is to examine the effects of endocrine therapy treatment on women diagnosed with breast cancer. We also want to evaluate the effectiveness of an online tool with educational content about your diagnosis.***

You will be asked to complete four interviews over the course of the year that will ask you about your feelings and your health. You will also complete an 8-week long web-based health program, participating in weekly 1.5 hour guided discussions with other breast cancer survivors participating in the study. During this time you will also be asked to use a special MEMS cap for your medication to track your usage of it. This cap only collects information about how many times you open your bottle, and all the information that we gather is deidentified. During the in-person interview appointments, the study team will download this information from your MEMS cap and save it to a MEMS cap software. The study team will also access your pharmacy records to track when you had your endocrine therapy refilled.

We expect that you will be in this research study for approximately 12 months; a first interview, an 8 week intervention, an interview at the end of the intervention, an interview 6 months after you were consented and an interview 12 months after being consented. The primary risk of participation is that the questions and assessments could make you feel uncomfortable or distressed. You are able to withdraw your consent at any point in time if you feel uncomfortable. The main benefit is that your participation may help you have a better understanding of how your disease and treatment affect your life so that it can aid in making decisions about emotional support for you.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are a woman diagnosed with breast cancer and you are currently undergoing treatment. You have been identified as eligible through our telephone screening process.

How many people will be in this study?

We expect about 80 people will be in this research study.

What should I know about participating in a research study?

- Someone will explain the research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

What happens if I say, "Yes, I want to be in this research"?

- If you agree to participate in this research, a member of our research team will schedule a time to meet with you at the Department of Medical Social Sciences at Northwestern University, or another convenient location.
- We will also ask you to complete a questionnaire on demographic information. The information about yourself that you gave us as part of the first phone screener will also be used for study data.
- We will show you how to use the website and give you a brief orientation. After this you will complete your first interview, comprised of a set of questionnaires assessing your health status, that will take approximately 90 minutes.
- We will ask your permission to contact your pharmacy and see how often you refilled your medication. If you change your pharmacy over the course of this study, we will ask you to fill out a form for your new pharmacy either in person or through the mail via a pre-paid envelope.
- We will also ask you if we can use some of the information in your medical records as part of the study, including medical and treatment-related information. This information will be used to better understand the information collected during this study. Granting us permission to use this information from your medical records is a prerequisite for participation.
- You will receive a MEMS cap for your medicine container and will be instructed on how to use it properly. Information from your MEMS cap will be downloaded to a MEMS cap software during each of the in-person visits. However, all of this data is de-identified and does not use any personal information about you such as your name or birthday.
- Immediately after your first interview you will be randomly placed into one of two groups; the two groups receive different treatments designed to help you cope with the side affects of your endocrine therapy. The group you will be assigned to will be chosen by chance, like flipping a coin. Neither you nor the study team will choose what intervention you get. You will have an equal chance of being assigned to any given group. You will not be told which group or intervention you are getting, however your study team will know. Both groups will receive treatment, but the treatments will be slightly different.
- This treatment consists of an 8 week program run by the project website.
- Each week you will participate in a live video focus group with a trained mediator on the website lasting approximately 90 minutes.
- We will send you texts through a secure study Outlook the day before your focus groups to remind you to join them.
- At 4 weeks into the program, you will complete an online questionnaire that will last 10 minutes long and will be completed directly on the website.
- At the end of the 8 week long program, you will complete an assessment similar to the one you completed at the consenting interview. You will also give us information about your experience with the site itself. Your input in this interview will help us improve the site in the future. This interview will last approximately 45 minutes.
- Six months after your first 'baseline' interview, you will conduct another interview like the first (30 minutes.)

- You will complete your final 30 minute interview 12 months (1 year) after your baseline interview.
- You will be compensated after each interview and will receive a total of $300 for completing the entire process.

Event	Estimated Time Involved
Baseline	90 Minutes
Weeks 1-8 - 4 week questionnaire	90 minutes per week 10 minutes
8 week follow-up	45 minutes
6 month follow-up	30 minutes
12 month follow-up	30 minutes

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include learning more about your diagnosis and treatment, which is associated with better long-term health outcomes.

Although it is possible that you will benefit from sharing your cancer experience, we cannot guarantee a direct benefit.

Is there any way being in this study could be bad for me?

Your participation does not involve any risks other than what you would encounter in daily life. Some of the questions we ask might make you feel some discomfort. If you are uncomfortable, you are free to decline or to skip any questions. If the investigator feels you are experiencing a lot of distress, we will provide you with a referral for psychological support.

We do not forsee that the use of the website will cause distress, it's meant to increase self-efficacy in communication and coping with emotions, as well as increase knowledge about breast cancer. It contains information from legitimate sources, and it has been vetted by multiple clinical psychologists and doctors at Northwestern University. However, the use of the website does not replace your standard of care provided by a doctor. You should inform your physician whenever you make changes to your health regimen.

In an emergency, or if you have an urgent medical or mental health issue, call 911. If you have less pressing questions regarding the website you can contact us, but note that it could take us up to 72 hours to respond.

Northwestern will do everything we can to protect your privacy; however, we cannot guarantee that the other participants in the focus group will respect that confidentiality.You may know some of the members of your internet-based group, have friends in common, or go to the same doctor. You may live in the same area or frequent the same places, and thus you may run into each other outside the group. As such, there is the potential for loss of confidentiality as part of

group involvement. It is very important to keep very strict confidentiality about what is said in the internet-based meeting so people can speak naturally in the group. When speaking with others outside the group, you can feel free to talk about what you experienced, what you learned, or what you felt in the group, but please don't talk about other people's experiences, even without using their name.

Similarly, while any information in the website is protected, there is some possibility that the use of the website in public could cause loss of confidentiality since those around you could see what you are inputting or looking at within it. Throughout the study, you will be encouraged to join the remote focus groups in private to protect your own and other's confidentiality. Also, there is a risk if you try to access the website on your smartphone or tablet while walking or driving since it could involve injury or accidents. Therefore, you are not permitted to use the website while walking or driving.

What happens if I do not want to be in this research?

Participation in research is voluntary. You can decide to participate or not to participate.

Instead of being in this research study, your choices may include not participating in this study.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time and it will not be held against you.

If you decide to leave the research no more information will be collected from you. If you decide to leave the research, contact the investigator so that the investigator can ask if the information already collected from you can be used.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the National Institutes of Health, the IRB and other representatives of these institutions.

If identifiers are removed from your identifiable private information collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Study information, such as baseline and follow-up assessments and clinical information from the electronic health record, will be documented in REDCap, a secure data capture service in cooperation with Northwestern Medicine that includes a secure connection. Terms of service may be viewed at https://confluence.nubic.northwestern.edu/display/RUCP/REDCap+Security.

Additional study information, such as your symptom updates and program usage (e.g., number of log-ins, interaction with the program), will be collected through the website that was developed by Bright Outcomes on a server hosted at Connectria Inc. All program data will be encrypted and transferred to password-protected Northwestern servers. Besides the email required for log-in, no other private health information will be collected or stored within the website. If you do not have an email address, or do not wish to use your personal email, we will create a temporary email address using pseydonyms which will be deleted at the end of the study. The following is a complete list of information that the website will collect:

- Email address
- Username information
- Login events
- Responses to activities on the website and when your responses were submitted
- Page view events (what page you viewed on the website and when it was viewed).

Terms of service may be viewed at https://oncotool.brightoutcome.com/#/terms-conditions

After you complete your Pharmacy's HIPAA authorization form, study staff will reach out to your pharmacy and request records related to your endocrine therapy treatment. Specifically we will be collecting:

- The date of your endocrine therapy prescription
- Endocrine therapy Name
- Prescribing Provider Information
- Pharmacy Location and Phone number
- Dosing Information and Instructions
- The fill/refill date, pill quantity, and the amount you paid for your medication

Your study data will be identified by a unique participant identification number. All information will be securely kept on a password-protected database on Northwestern servers. Your data is password-protected and secured according to strict HIPAA guidelines. Only IRB-approved members of the study team will be authorized to view and handle research data. Upon completion of the study, any possible participant identifiers will be deleted. The results of the research study may be published as a summary and not connected to identifiable participants; your name will not be used.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Cancer Institute which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you 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.

A description of this clinical trial (NCT03849573) will be available at http://www.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.

HIPAA Authorization:

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Information about your cancer diagnosis date, stage and recurrence
- Results of physical examinations (staging, diagnostic results)
- Cancer treatment history, including medications and surgery
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about medication or drugs
- Billing information

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information may be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office.

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.

- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- The National Institutes of Health, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Dr. Betina Yanez
Northwestern University Feinberg School of Medicine
Department of Medical Social Sciences
633 N. Saint Clair, 19th Floor, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before

files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without giving my OK?

The person in charge of the research study can remove you from the research study without your approval if they judge that it is in your best interest to do so.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

Compensation: If you agree to take part in this research study, we will pay you $300 for your time and effort. You will be paid $100 cash for your first interview, $50 for your second interview, $50 for your third interview and $100 for your fourth interview, within 30 days of completing each interview. You will be paid with cash or a pre-loaded gift card depending on whether you complete the interview in person or over the phone. Furthermore, in the event that you require transporation, we would reimburse up to $7.00 for your travel expenses (e.g. cost of bus or train to Northwestern), or provide you with a ticket for parking at a designated lot by our office.

If you agree to participate in this study, the MEMS cap must be returned after completion of the final meeting. If you decide to complete the a meeting over the phone, you will be able to return the MEMS cap with a pre-paid envelope that we will send you. If damage occurs to the equipment as part of the study or if the equipment is lost, you will NOT be liable. You may choose not to participate in the study if you feel you cannot safely return the study equipment. If the cap is lost, please contact the study team as soon as possible so that we can send you a replacement in the mail.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has affected you in some way, talk to the research team at Northwestern University. If you have questions, concerns, or complaints talk to the Principal Dr. Betina Yanez at 312-503-5341 and Diana Buitrago at 312-503-2866.This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study.

Consent to Participate in Research

Your signature documents your permission to take part in this research.

_____ _____

Signature of participant Date

_____

Printed name of participant

_____ _____

Signature of person obtaining consent Date

_____

Printed name of person obtaining consent