

Consent to Participate in Research

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Title of Research Study: A Research Study for Latina Women After Breast Cancer

Investigator: *Betina Yanez, Ph.D.*

Supported By: The National Cancer Institute.

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 compare two health applications. These health applications are delivered via phone and are designed to address the quality of life of Latina women after completing breast cancer treatment. Through this study we aim to 1) test the usefulness and helpfulness of (satisfaction with) the application you are assigned to, and 2) examine the effects of the application you are assigned to on your quality of life and wellbeing. You will be asked to be part of three study meetings: the first meeting is in-person but may also be done over the phone, and the final 2 meetings are over the phone. The first two meetings will last 1 hour each, and the final meeting will last 30 minutes. Additionally, you will participate in an 8-week field trial of the phone application you are assigned to. During your first 6 weeks of participation, we will request that you access your phone application for about 2 hours each week on your own schedule, and during the last 2 weeks, you can use the application at your own discretion. During the first 6 weeks, we will also set up a weekly call that will take about 15 minutes. We expect that you will be in this research study for a total of 8 weeks. There are no significant risks associated with this study. The main benefit is access to health information designed for women diagnosed with breast cancer.

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 Hispanic/Latina woman who has completed treatment for breast cancer and meets the study's eligibility criteria.

How many people will be in this study?

We expect that about 90 people will participate in this phase of our 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 study, you will be assigned by random assignment (by chance - like flipping a coin) to one of the two phone applications. You have an equal chance of being assigned to either of the two applications.

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When you are assigned to one of the applications, we will set up a time to meet in person to conduct the consent procedures and the first in-person meeting for this study. If you are unable to meet in person for this first meeting, a meeting over the phone may be set up. There are 3 meetings in total, the first two will last about an hour, and the final one about 30 minutes. The first meeting will take place at our laboratory space within the Department of Medical Social Sciences at the Feinberg School of Medicine, or at a location convenient for you, or over the phone, and the final two meetings will be conducted over the phone, unless you would like to have our last meeting in person at our Northwestern office.

As part of the first meeting we will ask you to complete a questionnaire on demographic information. Additionally, if you consent to being part of our study, the information you've already given us during the eligibility screening questionnaire completed over the phone will be retained as part of the study records. We will also ask you if we can use some of the information in your medical records as part of the study. This information will be used to better understand the information collected during your interview. Granting us permission to use this information from your medical records is a requirement for participation.

You will then complete a multiple choice interview. The questions will focus on coping with breast cancer, breast cancer knowledge, and your needs during and after treatment. Finally, we will go through an orientation of the application. You will be given the option to either use your own phone to download the application or to borrow a study phone. Once downloaded, we will create a unique account with you. Only an email address and password is required to register. 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 pseudonyms which will be deleted at the end of the study.

For the first 6 weeks of the study, you will be instructed to access the application on your own for an average of 2 hours per week, and we will ask you to complete a short questionnaire once a week; completing these questions should take 2-3 minutes.

During the first 6 weeks we will also schedule a weekly call that will last 15 minutes. This call is meant to guide you through some content you might not be aware of, and to see if you have any difficulties accessing the application. The weekly calls will be audio-recorded so we can remember what you told us over the phone. We will text you on the day before your call to remind you of your call, or to notify you if there are any changes. Receiving texts is required for participation. If you are borrowing a study phone, we can send you messages to the study phone. These text messages are sent from a secure account used for texting and they would include general details used for your appointments.

After the completion of the first 6 weeks, we will schedule a second meeting over the phone. During this second meeting, you will complete a follow up multiple choice interview consisting of the exact same questions from your first interview, as well as questions about your experience using the application.

For the final 2 weeks of the trial, you will be instructed to use the application at your own discretion, and you will not be required to complete a weekly questionnaire or call. After the final 2 weeks, we will have our third and final phone call (in-person meeting if you choose to travel to Northwestern) that will last 30 minutes. During this meeting we will ask you some of the same questions from the second meeting, and may ask you to remove the application from your personal phone, or ask you to mail the study phone if applicable. We cannot guarantee you will be able to keep the application you are assigned to after the initial 8 weeks of use, however if you would like, we can offer to let you use the one you were not assigned to for a similar amount of time. If you borrowed a study phone, the phone will be reset to the factory setting, and none of your information will remain on the phone. If you used a study phone, upon your request we will mail a copy of the content found in the application you did not receive.

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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, you may benefit from the testing of these phone applications as there is some preliminary evidence that health information such as what you will be accessing through the applications can improve quality of life and health related knowledge. Although the main purpose of this study is to assess the usefulness and effectiveness of the phone applications at improving wellbeing and quality of life, based on previous research, it is possible for you to have some benefits.

In our previous research, we have found that former cancer patients have reported medium to high satisfaction with learning about healthy living and have reported that they have been able to incorporate the information on healthy living into their everyday routines.

Additionally, the information gained from this study may benefit society by providing information to help other patients and health care providers to better assist Latina women to manage their symptoms and to improve their quality of life after their treatment.

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

Your participation in the three study meetings 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 foresee that the use of the application 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 only from legitimate sources, and it has been vetted by multiple clinical psychologists and doctors at Northwestern and the University of Illinois at Chicago (UIC). However, the use of the application 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 application you can contact us, but note that it could take us up to 72 hours to respond.

Finally, there can be risks associated with your individual use of the application. There is a slight risk of loss of confidentiality. While any information in the application is protected, there is some possibility that the use of the application in public could cause loss of confidentiality since those around you could see what you are inputting or looking at within the app. Also, there is a risk if you try to use the smartphone while walking or driving since it could involve injury or accidents. Therefore, you are not permitted to use the application while driving or walking.

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. You can withdraw from this study at any time. Choosing not to be in this study will not negatively affect your right to any present or future medical treatment.

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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.

At any time during your participation, you may decide to withdraw from the study. If you decide to leave the research please tell the research team first. If you decide to leave the research, your regular care will not be affected nor will your relations with Northwestern University, the University of Illinois at Chicago (UIC), your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

If you withdraw no more information will be collected from you. If you indicate you wish to withdraw, the investigator will 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 IRB and other representatives of this institution, as well as the research staff at UIC that has been approved to conduct this study by the Northwestern IRB. Also if necessary, the information may be looked at by the UIC Office for the Protection of Research Subjects to protect your rights or welfare (for example, to monitor the research or consent process) or if required by law.

Any study records that can identify you, such as this informed consent, will be kept confidential. They will be stored separately from your interview under lock and key. Any study records used to collect information about you such as interviews, questionnaires, audio recordings or phone application information will not have any identifiable information and will also be kept under lock and key, or protected by a password. Any information collected will be accessible only to the research staff on this study for purposes of analysis.

The data collected via the smartphone will be transmitted using Transport Layer Security (TLS) encryption to prevent eavesdropping and tampering of information and data while it is transmitted directly to the Northwestern sever. At the end of participation, the application will be deleted from your phone, and no other information will be collected. For participants that borrowed a study phone, the application will also be deleted from the phone and the phone will be reset to the factory setting.

All information collected by the phone application will be immediately transmitted to CBITs, this application does not save any data to the phone's memory, and it does not collect any data from the phone besides the data entered into the application by you, or through your interaction with the application. Besides the email required for login, no other private health information will be collected by this application or stored by the application. 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 pseudonyms which will be deleted at the end of the study.

The following is a complete list of information that the phone application will collect:

- An email addresses
- Login events
- Questionnaire answers and when the questionnaire form was submitted
- Page view events (what page you viewed in the application and when it was viewed)

The results of the research study may be published, but your name will not be used or associated with the data at any time.

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A description of this clinical trial (NCT03645005) 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 see this Web site at any time.

HIPAA Authorization:

In order to participate in this study, we need to obtain your health information from you medical providers. Your signature on this consent with HIPAA Authorization is the means for getting access to that information. 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:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about medication or drugs
- Genetic health information: BRCA (BReast CAncer susceptibility) gene testing/results (to assess increased breast cancer risk)

Those persons who get your health information may not be required by Federal privacy laws to protect it.

Under the HIPAA Authorization, the following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Rehabilitation Institute of Chicago (RIC), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), 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, UIC, 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]. During the conduct of the research, the researchers may use or share your health information with the following:

- 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.
- Authorized members of the UIC research team approved by the Northwestern Institutional Review Board (IRB). Also if necessary by the UIC Office for the Protection of Research Subjects to protect your rights or welfare (for example, to monitor the research or consent process) or if required by law.

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- Authorized members of the DePaul University research team approved by the Northwestern Institutional Review Board (IRB).
- Clinical affiliates, including but not limited the Rehabilitation Institute of Chicago (RIC), 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.
- The National Cancer Institute (NCI), 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.

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

Unless you revoke your consent, it will expire at the end of the research 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:

PI's Name: Dr. Betina Yanez
 Institution: Northwestern University
 Department: Medical Social Sciences
 Address: 633 N St Clair St, 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.

What else do I need to know?

Compensation: If you agree to take part in this research study, we will pay you \$100 for your time and effort. After the initial meeting is completed, you will receive \$30 in cash out of the possible \$100. If the first meeting is completed over the phone, a \$30 Visa gift card will be mailed to you. After the last questionnaire, you will receive the remaining \$70. You will have two different options to receive the remaining \$70: (1) a Visa gift card that will be mailed to your home address, or (2) cash if you would like to meet us in person.

If you decide to use your own phone to download the application, you will be reimbursed \$15 for data usage which will be added to the option you selected (cash or gift card) on the day of your 3rd

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appointment. For your first in-person appointment, you will also be reimbursed for travel costs (up to \$7 for the bus or train to Northwestern in cash), or receive a parking pass for one of our designated lots.

Additionally, if you complete all 3 study appointments, you will be entered in a study raffle to win an additional \$50. If you win, you have 2 options to receive the \$50: (1) a Visa gift card that will be mailed to your home address, or (2) cash if you would like to meet us in person. . The raffle will occur 3 months after your study completion, and we will contact you on the day of the raffle to notify you.

Although we cannot guarantee you will be able to keep the application you were assigned to after the initial 8 weeks, if you would like, we will offer you the other version of the application for a similar amount of time. Due to the cost of hosting the applications, we cannot guarantee indefinite access to either one of them.

If you borrow a study phone to participate in this study, this research equipment must be returned after completion of the final meeting. If you decide to complete the last meeting over the phone, you will be able to return the study phone with the mailing materials that were provided to you during our first meeting. If damage occurs to the equipment as part of the study or if the equipment is stolen from you (documented), you will NOT be liable. You will only be responsible for the cost of the equipment, if the equipment is lost or damaged due to negligence. You may choose not to participate in the study if you feel you cannot safely return the study equipment. If you would like a headset to interact with the application, it will be provided free of charge.

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, Department of Medical Social Sciences, 633 N. St. Clair St Suite 19-77, Chicago IL, 60611. You can also call Dr. Betina Yanez at 312-503-5341, or Alma Diaz at 312-503-0452.

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.

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Signature for Adult 18 or older

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