Informed consent form for: To Enhance Breast Cancer Survivorship of Asian Americans

NCT #: NCT02803593

IRB approval date: July 21, 2020

You Are Being Asked to Be in a Research Study

To Enhance Breast Cancer Survivorship of Asian Americans

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 330 people who are being studied, at Emory and elsewhere.

Why is this study being done?

This study is being done to answer a question on whether a technology-based information and coaching/support program is effective in enhancing survivorship experience of Asian American breast cancer survivors (TICAA). Asian American breast cancer survivors tend to suffer from symptoms and pain due to their cultural background. The TICAA program that we are testing is designed to help Asian American breast cancer survivors by providing information and coaching/support. The research team wants to know if the program enhances survivorship experience of Asian American breast cancer survivors as designed. You are being asked to be in this research study because you have self-identified as 1) an Asian American woman aged 21 years and older who has had a breast cancer diagnosis; 2) can read and write English, Mandarin Chinese, Korean or Japanese; 3) have access to the Internet; and 4) identify your subethnicity as Chinese, Korean, or Japanese.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate in the study for 3 months. The researchers will ask you to do the following depending on the group that you are randomly assigned.

If you are assigned to the group who is asked to use the TICAA program (Group 1), your involvement will consist of the following: (a) you will be asked to fill out the questionnaire at 3 times, and about 30 minutes are usually needed to complete the Internet survey questionnaire at each time (if requested, paper-and-pencil questionnaires will be provided/used, or research staff will assist in administering the Internet surveys over the phone.); (b) you will be asked to use the online resources that are provided by the research team; and (c) you will be asked to use the TICAA program for 3 months.

If you are assigned to the group who is not asked to use the program (Group 2), your involvement will consist of the following: (a) you will be asked to fill out the questionnaire at 3 times, and 30 minutes are usually needed to complete the Internet survey questionnaire at each time (if requested, paper-and-pencil questionnaires will be provided/used, or research staff will assist in administering the Internet surveys over the phone.); (b) you will be asked to use the online resources that are provided by the research team for 3 months.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question on if the TICAA program is effective in enhancing Asian American breast cancer survivors' survivorship experience. You may not directly benefit from participation in this study; however, you will gain some knowledge and peer support from using the program. Also, you may get some satisfaction from knowing that the information you provide will assist health care providers in developing and refining a culturally competent information and coaching/support program for Asian American breast cancer survivors. Further, you may gain additional knowledge by using the information provided as online links to additional resources related to breast cancer that will be part of the project Website.

What are the risks or discomforts I should know about before making a decision?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
You WILL NOT have to pay for any of the study procedures.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Take time to consider this, and talk about it with your family and friends.

EMORY UNIVERSITY | Institutional Review Board
Research Administration

Emory University
Consent to be a Research Subject

Title: To Enhance Breast Cancer Survivorship of Asian Americans

IRB #: IRB00117270

Principal Investigator: Eun-Ok Im**,** PhD, MPH, RN, CNS, FAAN, Nell Hodgson Woodruff School of Nursing

Funding Source: National Cancer Institute (National Institute of Health)

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this study is to learn more about the effectiveness of a technology-based information and coaching/support program (TICAA) in enhancing survivorship experience of Asian American breast cancer survivors.

Procedures

If you agree to participate:

1. Within 3-5 days, you will be asked to visit the Website of this project, join the project, obtain a copy of the informed consent form that provides general information about this project, and click the 'I agree to participate' button to give your consent to participate. The document you will read through the project website is the consent form. You can agree to participate after reading through it or can come back and provide consent at a later date. Once you give your consent to participate, you will be asked several questions to check if you are eligible to participate in the study.
2. If you are determined to be eligible for the study, you will be asked to register for the Website of this project. For registration, you will receive an email that asks for creating your own ID and password within 2-3 days once the research staff enrolls you in the Website. You should use the ID and password to log into the Website.
3. You will be randomly assigned to one of the two groups: one who will use the TICAA program (Group 1) and the other who will not use the TICAA program (Group 2). Then, you will be provided with an electronic instruction sheet on when you need to come back to the Website, fill out additional questionnaires, and/or use the TICAA program.

4. If you are in Group 1, you will be asked to fill out the first questionnaire as soon as you are determined as an eligible participant through the screening survey. It would take about 20 to 30 minutes to fill out the questionnaire. Then, you will be asked to use both the online resources and the TICAA program (which includes the education module and resource, online forum, individual coaching by chatting function in TICAA Website, phone call, or mobile chatting) whenever you want to use for 3 months. Every two weeks, you will receive emails containing reminders and thank you messages from the research staff. Then, you will be asked to fill out the next set of the questionnaire by the end of the first month. It would also take about 20 to 30 minutes to complete the questionnaire. Then, two weeks before the end of the third month period, Group 1 will be re-contacted by email and asked to fill out the next set of the questionnaire by the end of the third month (about 20 to 30 minutes to complete). When you complete the final set, you will be provided with a $50 electronic gift card.

5. If you are in Group 2, you will be asked to fill out the first questionnaire as soon as you are determined as an eligible participant through the screening survey. It would take about 20 to 30 minutes to fill out the questionnaire. Then, you will be asked to use the online resources (that are provided by the research team) whenever you want to use for 3 months. Then, you will be asked to fill out the next set of the instruments by the end of the first month; it would take about 20 to 30 minutes to complete the questionnaire. Then, two weeks before the end of the third month period, Group 2 will be re-contacted by email and asked to fill out the next set of the questionnaire by the end of the third month (about 20 to 30 minutes to complete). When you complete the final set, you will be provided with a $50 electronic gift card.

Risks and Discomforts

1. Participation in this study may be inconvenient, but there are no other discomforts involved. Some of the questions may make you feel uncomfortable or upset because of their personal nature. You are free to not answer any questions that you do not wish to answer or to stop taking part in the project at any time.
2. Any information that you provide and anything that you write in the project Website will be handled as confidentially (kept secret) as possible. Only the research team will have access to your information including your email address. Your email address will be used only for reimbursement for your participation, and kept in a locked cabinet separately from your research data. At the completion of the study, your email address will be completely eradicated. Answers you provide on the Internet surveys will not be shared with anyone unless you appear at risk of harm to yourself or others. Only the research team will have access to your information (your answers on the Internet survey), which will be directly saved in a computer file. Your name or any other information you provide will not be used in any reports or publications that will result from this study. However, because this is an online study, there is always the risk that outside agents (i.e., hackers) will try to access the Website. If they do, they may be able to identify you. This is not likely to happen, but it could. And the mobile chat function (e.g., Wechat, Line, Kakao Talk, Skype et al.) are not secure methods of communication, too.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

This study is not designed to benefit you directly. However, you will gain some knowledge and peer support from using the program. Also, you may get some satisfaction from knowing that the information you provide will assist health care

providers in developing and refining a culturally competent information and coaching/support program for Asian American breast cancer survivors. Further, you may gain additional knowledge by using the information provided as online links to additional resources related to breast cancer that will be part of the project Website.

Compensation

At the completion of your participation, you will receive a $50 electronic gift card for your participation in the study. Compensation will be prorated so that if a subject withdraws from the study, the subject will receive compensation for the parts of the study she completed.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include [the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance]. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you) may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

- The PI feels it is best for your safety and/or health-you will be informed of the reasons why.
- You have not followed the study instructions.
- The PI, the NIH, or the Office of Regulatory Affairs at Emory University can stop the study anytime

Contact Information

Contact [PI: Eun-Ok Im] at [redacted]:

- if you have any questions about this study or your part in it, or
- if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**

- If you agree to participate, please click the below button of "I agree to participate."