

## **Title Page:**

- **Full study title**  
To Enhance Breast Cancer Survivorship of Asian Americans  
Short study title: TICAA
- **Name, Title(s), and Department of Principal Investigator**  
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National Cancer Institute
- **Protocol version number and version date**  
June 3, 2020
- **NCT Number:**  
NCT02803593

## Background and Significance

Breast cancer is the leading cancer by site in Asian American women.<sup>1-3</sup> For some sub-ethnic groups, breast cancer is the leading cause of death.<sup>4-8</sup> Asian Americans have been reported to have higher relative risks and lower 5-year survival rates with increasing age at diagnosis, grade, and stage of cancer.<sup>1-3,9-11</sup> Furthermore, Asian American breast cancer survivors often carry significant physical and psychological burden; they rarely complain about their symptoms, delay seeking help until symptoms become severe, and seldom ask or get support due to their cultural values, beliefs, and language barriers.<sup>12-16</sup> Subsequently, they report a lower quality of life and fewer sources of information and support compared to Whites.<sup>1-3,6,9-11,17-19</sup> Here, a breast cancer survivor means anyone who has been diagnosed with breast cancer, from the time of diagnosis through the balance of her life.<sup>20</sup>

The Institute of Medicine report, *From Cancer Patient to Cancer Survivors: Lost in Transition*,<sup>21</sup> explicitly identifies the need of cancer survivors for information on symptom management, accurate surveillance of late and long term effects, psychosocial supportive interventions to promote well-being, and communication with health care providers. Yet, few interventions have been developed to meet the need of cancer survivors including Asian American breast cancer survivors.<sup>22</sup> Survivorship programs that are increasingly instituted at cancer centers have serious impediments to providing information and coaching/support because of the lack of staff time and insurance reimbursement.<sup>23,24</sup> Furthermore, the pressure of fast-paced clinical patient-provider interactions leaves little time for health care providers to provide up-to-date information and coaching or support for these women based on their cultural attitudes.<sup>12-16</sup> All these circumstances necessitate an innovative and creative delivery method of information and coaching/support.

A technology-based approach using computers and mobile devices (smart phones and tablets) promises to meet this necessity with high flexibility and accessibility, and minimizes the cost of the intervention in busy health care settings.<sup>25-27</sup> Also, a technology-based intervention that does not involve face-to-face interactions could work better for many women from cultures where breast cancer is still a stigmatizing experience.<sup>28-31,32-35</sup> Despite the high potential, few technology-based interventions are available for ethnic minority breast cancer survivors, especially for Asian Americans.<sup>36-45</sup> Therefore, based on Preliminary Studies (PSs), the research team has developed and pilot-tested a theory-driven technology-based information and coaching/support program that: (a) is tailored to Asian American breast cancer survivors by incorporating actual data on individual sub-ethnic groups cultural attitudes from PSs; (b) uses multiple languages; (c) provides both group and individual (real-time and personalized) coaching/support by culturally matched bilingual health care providers; (d) incorporates peer support through a social media function; and (e) integrates existing general and culture-specific evidence-based educational content from scientific authorities. Among over 71 sub-ethnic

groups of Asian Americans,<sup>46</sup> only three sub-ethnic groups (Chinese, Korean, and Japanese) were selected for the program development for the convenience of the approach (e.g., language). Within Asian Americans, Chinese are the largest sub-ethnic group,<sup>47,48</sup> Koreans are the fastest growing sub-ethnic group,<sup>47,48</sup> and Japanese are the sub-ethnic group at the highest risk of breast cancer.<sup>1,2,11,49</sup>

## Goals/Aims

The purpose of the proposed randomized intervention study is to test the efficacy of the technology-based information and coaching/support program for Asian American breast cancer survivors (TICAA) in enhancing the women's breast cancer survivorship experience.

The **specific aims** of the study are to:

**Aim 1.** Determine whether the intervention group (who uses the TICAA and the information on breast cancer by the American Cancer Society [ACS]) will show significantly greater improvements than the control group (who uses only the information on breast cancer by the ACS) in **primary outcomes** of the TICAA (needs for help, physical and psychological symptoms, and quality of life) from baseline (*pre-test*) to *Time Points 1 (post 1-month; primary)* and *2 (post 3-months; secondary)*.

**Aim 2.** Identify theory-based variables (attitudes, self-efficacy, perceived barriers, and social influences related to breast cancer survivorship) that **mediate** the intervention effects of the TICAA on the primary outcomes of the TICAA from baseline to Time Point 1.

**Aim 3 (exploratory).** Explore whether the effects of the TICAA on the primary outcomes are **moderated** by background factors and disease factors.

## Study Design

- Organizational structure of the study team:

This is a PI initiated R01 research project that is funded by the National Cancer Institute (National Institute of Health). Due to PI's move from Duke University to Emory University, the study is being transferred from Duke Univ. to Emory University. This is the fourth year of the total 5 year of funding. This IRB approval is needed for the grant transfer.

The study team includes the PI, 1 Co-Investigator, 1 Statistician, multiple Consultants, 3 interventionists and 1 or 2 research assistants. Except the consultants, all research team members will be Emory affiliated. The research team will conduct the study at School of Nursing, Emory University.

- Setting and location:

The settings of the study will include (a) online support groups including social media groups and (b) communities/groups for Asian Americans. Over 400,000 online support groups currently exist, each with up to 3,587 members.<sup>60-62</sup> They have become an important resource for researchers investigating cancer survivors residing in different geographic areas, both nationally and internationally.<sup>60-62</sup> Furthermore, potential participants could be easily recruited through the recruitment announcement services provided by social media (a fee is usually required though). For example, through a Facebook announcement, Altshuler et al.<sup>63</sup> recruited women from multi-ethnic groups (within 3 months) for a study on attitudes toward abortion. Yet, PSs also suggested that ethnic minority cancer survivors might not be easily recruited only through online support groups. Thus, communities/groups for Asian Americans (e.g., churches, organizations, health care centers, and professional groups, all of which are for Asian Americans) will also be targeted, which allows to recruit those who do not use online support groups or who do not have access to the computers. Ethnic minorities are more successfully recruited in churches and support/social groups with culturally specific memberships.<sup>64</sup> When communities/groups for Asian Americans in the U.S. were searched with Google, 1,170,000 communities/groups were retrieved, each with up to 30,298 members. In addition to these major recruitment settings, cancer registries throughout the nation (e.g., Texas and California) will be contacted to request the data, which will be used for identifying and reaching out to potential participants to send the study announcement and informed consent.

- Population to be studied:

The participants will be 330 self-reported Asian American women aged 21 years and older who have had a breast cancer diagnosis; can read and write English, Mandarin Chinese, Korean, or Japanese; and have access to the Internet through computers or mobile devices (smart phones and tablets). A total of 210 participants have already been recruited at Duke University and have completed their participation before the PI's move. A total of 120 participants will be newly recruited at Emory University. Those who are in treatment or not in treatment will be included because the TICA can be used by those in all stages of treatment. A specific fatigue level was not set because compared to those who do not have fatigue or have a low level of fatigue, those with a medium or high levels of fatigue would be more likely to need support through technology-based programs. We excluded those under 21 years old because their cancer experience would be different from adults.' An upper age limit was not set because elderly could be a good target group for technology-based programs because technology-based programs do not require physical

transportation and because women over 75 years old have the highest incidence rate of breast cancer.<sup>2</sup> Because using more than four languages is infeasible in a study (Dr. Meleis, Personal Communication), and given the diversity of Asian Americans, only four languages including English, Mandarin Chinese, Korean, and Japanese will be used. Mandarin Chinese is a primary language in China, Taiwan, and Hong Kong; Korean is the primary language in South Korea; and Japanese is the primary language in Japan.

- Recruitment:

First, Internet searches will be conducted using multiple search engines including Google, Yahoo!, and Bing to identify/verify online support groups and communities/groups for Asian Americans. Then, we will contact and ask administrators of the first 100 online support groups and 90 communities/groups for Asian Americans (30 for each sub-ethnic group) on the verified lists to post the study announcement on their sites or listservs and through instant messaging. We will also make supplementary/additional announcements through Web postings, listservs, and regular meetings with communities/groups that primarily serve Asian Americans of low SES to have an adequate number of Asian American breast cancer survivors from low SES (they are less likely to be recruited than those from middle or high SES in PSs). The communities/groups that primarily serve Asian American women of low SES will be identified through both Internet searches and recommendations by research team members including consultants. All the identified communities/groups will be contacted and asked to post study announcements with assistance from the research team members including consultants. Further recommendations will be sought from the communities/groups that are contacted. Then, the study will be announced in the newly identified communities/groups. If we do not recruit the target number, the study will be announced through an additional 20 online support groups and 30 communities/ groups for Asian Americans (10 per sub-ethnic group) each month. This process will be continued until the target number is recruited. In addition, we will utilize the cancer registries throughout the nation to contact potential participants and solicit their participation in the study.

A total of 330 Asian American breast cancer survivors will be recruited. Because information is limited on which to base power analyses, estimates are based on a two-sided Mann-Whitney test (assuming a uniform distribution) using an estimated effect size equal to 1/2 of a standard deviation, as suggested in the literature.<sup>65</sup> In addition to being clinically meaningful, large effect sizes demonstrated in PS4 suggest that  $0.5 \times SD$  is a statistically meaningful effect size to assume. Sample size is based on 80% power, and a type I error rate equal to 0.00625 to account for eight primary outcome measures modeled within the two primary aims (group main effects). Accordingly, group sample sizes of 105 each achieve 80% power to detect a difference of  $0.5 \times SD$  between group means overall in a single follow-up period. The primary analysis will be an assessment of differences by intervention group in changes from baseline to Time Point 1, or one month post intervention. A secondary analysis will include similar modeling for sustainability of

intervention effects, or for changes from baseline to Time Point 2. Assuming an attrition rate of 35% by the Time Point 2, 330 Asian American breast cancer survivors would be an adequate number for the study with multiple outcomes. Considering the attrition rates reported in the literature<sup>66-68</sup> and in PSs, the assumption of a 35% attrition rate is reasonable.

At the completion of their participation, the participants will be reimbursed with \$50 electronic gift cards for their participation. The reimbursement will be prorated. The participants will be allowed to choose “do not want to respond”, which will NOT be considered missing data. The amount was determined based on preliminary studies.

- Description of recruitment materials and their use

Sample study announcement, sample study announcement in flyer format, and flyer for TICAA recruitment will be distributed through and displayed on cancer support groups and communities/groups for Asian Americans.

- Describe the procedures for data collection

The data are mainly collected through the Internet survey questionnaire. When potential participants visit the project Web site (after receiving/reviewing a study announcement), they will be asked to review the informed consent. When participants click I agree to participate, they will have given their consent. Then, after checking them against the inclusion criteria and quota requirements, only those who meet the criteria and requirements will be automatically assigned a serial number, and randomized into two groups using an automated random number generator accessible through the Web site.

Then, the women will be asked to fill out the Internet survey questionnaire (if requested, paper-and-pencil questionnaires will be provided/used, or research staff will assist in administering the Internet surveys over the phone.) and sign up the Web site by creating their own ID and passwords. Whenever they visit the Web site, they need to use the ID and passwords to log in the site. If they want, they can change their ID and passwords. Then, both groups will be provided with an electronic instruction sheet on when they need to come back and fill out additional questionnaires and/or use the program.

Biweekly, the research team will send reminders and thank-you emails. Two weeks before the end of the 1st month, both groups will be asked to fill out the next set of the instruments by the end of the 1st month. Then, 2 weeks before the end of the 3rd month, both groups will be asked to fill out the next set of the instruments by the end of the 3rd month.

- Description of research instruments to be used (e.g., questionnaires, surveys, interview or focus group guides, scales)

Multiple instruments will be used: the Support Care Needs Survey-34 Short Form (SCNS-34SF),<sup>50</sup> the Memorial Symptom Assessment Scale-Short Form (MSAS-SF),<sup>51</sup> the Functional Assessment of Cancer Therapy Scale-Breast Cancer (FACT-B),<sup>52</sup> the modified Questions on Attitudes, Self-Efficacy, Perceived Barriers, and Social Influences (QASPS),<sup>53</sup> the Cancer Behavior Inventory (CBI),<sup>54,55,56</sup> the Perceived Isolation Scale (PIS),<sup>57,58</sup> the Personal Resource Questionnaire (PRQ-2000),<sup>59</sup> and 27 questions on background characteristics, level of acculturation, and disease factors. The reliability and validity of all the instruments have been established among Asian Americans. Cronbach's alpha of individual instrument ranged from .76 to .96 among Asian Americans.

- Describe any other study-related interactions or interventions: **The Intervention: The TICAA**

This study consists of two groups of research participants: (a) 165 Asian American breast cancer survivors (55 per sub-ethnic group) who do not use the TICAA, but use the information on breast cancer by the American Cancer Society (ACS)(a control group); (b) 165 Asian American breast cancer survivors (55 per sub-ethnic group) who use the TICAA and the information by the ACS (an intervention group). The ACS website includes information on treatment, prevention, genetics, causes, screening, testing, coping, clinical trials, research findings, and statistics related to breast cancer in multiple languages including Mandarin Chinese and Korean. At the completion of the study, both will be allowed to use or continue to use the TICAA.

***Theoretical Bases, Information Architecture, and Menus.*** The TICAA was developed based on the findings from PSs using the information mapping approach.<sup>69</sup> The TICAA is theoretically based on the Bandura's theory. Based on the Bandura's theory,<sup>70-72</sup> most self-management programs include coaching/support and information interventions as part of the program content.<sup>73</sup> Likewise, the TICAA includes group and individual (real-time and personalized) coaching/support by health care providers, peer coaching/support, and information to change the women's attitudes, self-efficacy, perceived barriers, and social influences. The TICAA uses a free-form matrix information architecture<sup>74</sup> and includes menus based on the three components (see below). Graphic User Interface controls<sup>75</sup> (e.g., push buttons, check boxes, drop-down lists) are used. Presentation styles (e.g., colors, menus, etc.) are tailored based on PSs.

***Technological Tools.*** The Ruby on Rails (ROR) framework (<http://rubyonrails.org>) and the Xen hypervisor (<http://xen.org>) were used to develop the TICAA. ROR is a web application framework based on the Model-View-Controller (MVC) architecture that can separate software logic and data handling from user interface.<sup>75</sup> Using ROR, multiple language versions as well as mobile versions of a web page generated from the same software logic can be easily handled, and this allows various interactive features.<sup>75</sup> The Xen hypervisor allows virtualization, which has the computer hardware to run multiple guest operating systems concurrently.<sup>76</sup> Each guest system, called a virtual machine, runs as an independent computer. By populating several virtual machines, if any of the virtual machines fail, the web service will be still available, which ensures the efficiency of the servers and the safety and security of the data.

**Components.** The TICAA has three components in four languages (English, Mandarin Chinese, Korean, and Japanese): (a) social media sites; (b) interactive online educational sessions; and (c) online resources. To incorporate cultural differences among three different sub-ethnic groups, three separate social media sites are designed for each sub-ethnic group. The sites provide a mechanism by which participants can connect to each other and share their own breast cancer survivor experiences with peers, have interactions with and get support from peers, and receive coaching/support from culturally matched peers and health care providers.<sup>77</sup> In each site, cultural tailoring will be done through incorporating both general and sub-ethnicity-specific materials to discuss and culturally appropriate examples from PSs. The sites will incorporate Asian cultural values related to family (e.g., family as the center of the women's daily life) and the collectivistic values for Asian women as a way to frame discussions and to present content. Each site consists of a social media function (like the timeline of *Facebook*), a chat function with a culturally matched bilingual interventionist and a symptom log function. Interventionists are required to have a bachelor's degree in a health-related field and be bilingual. We will have a registered nurse (RN) monitoring or supervising the coaching/support provided by the interventionists. The RN will provide consultation to the interventionists while consulting with two MD consultants. For the intervention period, weekly group and individual coaching/support by culturally matched bilingual interventionists will be provided. Group coaching/support through the social media function will not have time limits because it will be based on asynchronous interactions. Yet, real-time and personalized individual coaching/support will be provided in a specific designated time period (each participant sets a specific time period for getting individual coaching/support) by the chat function. In addition, the use of phone calls and mobile chat functions (e.g., Wechat, Line, KaKao Talk, Skype et. al) as supplementary methods for individual coaching/support is permitted for the study-related communications. Group coaching/support will start once the first 10 women per sub-ethnic group are enrolled, but individual coaching/support will start as soon as a participant is enrolled. Starting the group coaching/support with 10 women is reasonable when considering that 10~30 are usually an adequate number for a focus group, and group cohesiveness needs to be established.<sup>78</sup> Each week, the interventionists will post at least 5 group messages related to each topic to give group coaching/support, and send at least 1~2 message(s) to each participant for individual coaching/support. Coaching/ support will focus on enhancing breast cancer survivorship by changing cultural attitudes, building self-efficacy, minimizing perceived barriers, and enhancing social influences through multiple ways (see Table 1). Messages in other languages will be translated into English, and those in English will be translated into other languages (using both Google translator and daily reviews/corrections by the bilingual interventionists with consultation of professional translators). The interventionists will minimally interfere the interactions among the participants.

**A total of 15 interactive online educational sessions** (users can choose the content and ask questions and/or provide feedback by clicking buttons on the menu) provide information about general and sub-ethnicity-specific topics related to breast cancer survivorship. These sessions are also available in the four languages (already translated using the standard-back translation process<sup>79,80</sup>). The content is differently constructed by sub-ethnic group based on the cultural findings from PSs. For example, because Chinese women tended to use Chinese herbal medicine for their symptom management in PSs, we have added an education module on Chinese herbal medicine for Chinese participants. These sessions will provide correct and updated information on breast cancer and treatment/management strategies so that stigmatization could be reduced by



correcting misinformation. Culturally relevant contents (e.g., Red Ginseng, herbal medicine, Acupuncture, etc.) were also incorporated into the sessions. Finally, **sub-ethnicity-specific online resources** include 35 Web links to resources related to breast cancer survivorship in English, Mandarin Chinese, Korean, and/or Japanese from scientific authorities and from general and sub-ethnicity-specific health organizations/institutes. General resources will be available to all groups, but sub-ethnic-specific resources will be available only for the applicable group. Six experts reviewed the TICAA against the criteria for rigor in cross-cultural research.<sup>81,82</sup>

**Table 1. A Summary of the TICAA Components**

Intervention Component	Working Mechanisms	Concepts	Selected Examples of Intervention Activities
Social media sites	Sub-Ethnic-Specific Coaching/Support and Information	Attitudes	<ul style="list-style-type: none"> <li>- Weekly introduce and discuss a new topic related to breast cancer survivorship (from the educational sessions and online resources).</li> <li>- Initiate and promote individual and/or group dialogues to discuss breast cancer survivorship experience within their specific cultural contexts.</li> <li>- Provide feedback on the discussion by providing sub-ethnic-specific examples from PSs (e.g., breast cancer as a genetic disease, stigma).</li> <li>- Correct misinformation by providing most updated information.</li> <li>- Help identify the areas that need more information.</li> <li>- Address any general and sub-ethnic-specific concerns, and provide individual and group feedback on breast cancer survivorship.</li> </ul>
		Self-efficacy	<ul style="list-style-type: none"> <li>- Support participants in identifying culturally appropriate and acceptable ways to manage their needs for help.</li> <li>- Individually work with the women to set goals that gradually try several strategies to manage their needs for help (e.g., promoting physical activity, changing poor eating habits, learning to search the Internet, etc.) in culturally appropriate and acceptable ways.</li> <li>- Provide examples of symptom management strategies that can be easily used in daily life (general and culture-specific).</li> <li>- Individually help set the weekly goal of symptom management and monitor their symptoms using the symptom log (date, symptoms [frequencies and severity], changes in health status &amp; medication, usages of any strategies, and effectiveness of the strategies)</li> <li>- Provide individual feedback on: (a) calculated mean frequencies and severity of symptoms for the week reported; (b) symptom strategies used in the prior week; (c) trends in symptoms experienced by the women; and (f) suggestions for the next goal.</li> <li>- Help understand the educational sessions and resources (Q&amp;A) individually and as a group (in each sub-ethnic group).</li> </ul>
		Perceived Barriers	<ul style="list-style-type: none"> <li>- Initiate dialogues to discuss general and cultural-specific barriers.</li> <li>- Support participants in identifying culturally appropriate ways to recognize and manage breast cancer survivorship in daily life.</li> <li>- Use specific educational modules related to perceived barriers to breast cancer survivorship and tips in managing their needs for help in daily life (with sub-ethnic-specific examples from PSs).</li> </ul>
		Social Influences	<ul style="list-style-type: none"> <li>- Moderate peer interactions and group dialogues in each sub-ethnic group.</li> <li>- Provide individual and group support to enhance understanding on materials related to breast cancer survivorship.</li> </ul>

Interactive online educational sessions	Information	Attitudes	<ul style="list-style-type: none"> <li>- Promote culturally matched peers' interactions and feedback on breast cancer survivorship and management strategies for their needs for help.</li> </ul> <i>Providing information/knowledge on (examples):</i> <ul style="list-style-type: none"> <li>- “What do you know about breast cancer”/ “What’s new about breast cancer treatment”/ “After treatment topics”/ “Facts for life”/ “Genetic testing”</li> </ul>
		Self-efficacy	<i>Providing information on (examples):</i> <ul style="list-style-type: none"> <li>- “Complementary and alternative medicine for breast cancer”/ “Breast cancer pain”/ “Chinese herbal medicine”/ “Insomnia among breast cancer survivors”/ “What to know about osteoporosis and pain”</li> </ul>
		Perceived Barriers	<i>Providing information on (examples):</i> <ul style="list-style-type: none"> <li>- “What breast cancer survivors need to know”/ “Talking about breast cancer and cancer pain”/ “After treatment topics (general and culture-specific)”/ “Grief, mourning, and bereavement”/ “Post trauma stress disorder and breast cancer”</li> </ul>
Online Resources	Information	Attitudes/ Self-efficacy/ Perceived Barriers	<i>Culture specific resources (Examples of Korean-specific resources)</i> <ul style="list-style-type: none"> <li>-Korean cancer society (all about living with cancer)/ Asan medical center (breast cancer)/ Korean breast cancer foundation (breast health)</li> </ul> <i>General resources (examples):</i> Patient Summary on Pain by the NCI/ Pain Control: A Guide for Those With Cancer and Their Loved Ones by the American Cancer Society/ Cancer Pain Treatment by International Association for the Study of Pain

○ Describe processes for translating

The study announcement, informed consent sheet, the TICAA, and Internet survey questionnaires will be available in four languages. Mandarin Chinese, Korean, and Japanese versions have already been prepared using the standard translation and back-translation process by professional translators.

A total of 15 interactive online educational sessions provided to the intervention group are also available in the four languages (already translated using the standard-back translation process<sup>79,80</sup>).

In addition, messages used in the intervention in other languages will be translated into English, and those in English will be translated into other languages (using both Google translator and daily reviews/corrections by the bilingual interventionists with consultation of professional translators). The interventionists will minimally interfere the interactions among the participants.

○ Informed Consent Process:

The participants will be able to consent at any time after reviewing the informed consent sheet on the project website. They are free to go and come back later and consent if needed. **Participants**

will be informed that their participation is voluntary, and they can withdraw their participation at any time.

The reason for waiving the standard signed consent is multiple. First, we believe that it is unnecessary to meet with participants or to mail hard copies of the informed consent form for the sole purpose of obtaining signed consent. Second, obtaining signed consent from the participants across the nation raises a feasibility issue related to mailing and possible follow-up phone calls. Third, previous studies indicated that ethnic minorities including Asian Americans did not wish to sign a written consent for a historical reason: For example, in Korea, data from surveys were once used to identify tax fraud, and some people's honest answers on the survey were used to assess an additional tax. This Internet-based consent process has been used in all previous studies by the PI without any issues or concerns from participants or research staff members. The previous studies by the PI, which compared the paper-and-pencil survey with the Internet survey questionnaire, showed that the Internet-based consent process was similar to that of the paper-and-pencil survey in terms of its ability to explain the study and respond to questions from participants. Interestingly, some participants in the previous studies indicated that they preferred Internet communications to ask questions about the study because Internet communications are asynchronous (they could ask questions at any time) and e-mail is a written form of communication.

When potential participants visit the project Web site, they will be asked to review the informed consent form that provides general information on the proposed project, including: (a) the purpose of the study, (b) staff on the study, (c) the data collection period, (d) potential physical and psychological risks involving inconvenience, confidentiality, and invasion of privacy, (e) their rights to withdraw, (f) how to maintain complete confidentiality (using IDs and passwords), (g) what they are being asked to contribute to the study, and (h) how their participation will be reimbursed. The consent process will be automatic through the project website; the participants will be asked to click "I agree to participate" after reviewing the informed consent sheet that is loaded on the project website.

- Potential Risks/Discomforts to Study Participants and measures to prevent occurrence:

There are no risks of injury or bodily harm. There are no risks to employment/employability, reputability, financial standing, and/or criminal/legal status. However, participation in this study may be inconvenient, and some of the questions may make the participants uncomfortable or upset; however, the participants are free to decline to answer any questions if they do not wish to answer and to stop participating in the project at any time.

The participants' records will be handled as confidentially as possible. The collected data will remain confidential unless a participant appears at risk of harm. Only the research team will have access to the study records, which will be directly saved in a computer file format called ASCII. No individual identities will be used in any reports or publications that will result from this study. However, as an online participant in this research, the participants will always run the risk

that outside agents, such as hackers will try to access the site, and if they do, the participants may be identified.

- Benefits:

The participant may not directly benefit from participation in this study; however, she will gain some knowledge and peer support from using the program. Also, she may get some satisfaction from knowing that the information she provides will assist health care providers in developing and refining a culturally competent information and coaching/support program for Asian American breast cancer survivors. Further, she 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 Web site.

- Compensation for time and effort:

At the completion of their participation, the participants will be compensated with \$50 electronic gift cards for their participation. The compensation will be prorated. The amount was determined based on preliminary studies.

- Data Analysis: Data Management and Monitoring:

The data will be stored on research dedicated, secure folder, firewall protected servers maintained by Emory University, IT office. Subsequently, the security and safety measures to protect the data will just follow those of the Emory University, IT office. All documentation related to the study will be stored in a locked cabinet file in a secured office that is only accessible to approved doctoral fellows and faculty.

- Plans for analysis, statistical and/or otherwise:

Data analysis will be conducted at Emory University, School of Nursing. Data collected through the Internet will remain confidential unless a participant appears at risk of harm. Only the research team will have access to the study records, which will be directly saved in a computer file format called ASCII. No individual identities will be used in any reports or publications that will result from this study.

**Preliminary Analysis & Missing Data.** Serial ID numbers will be assigned and attached to the data. Descriptive statistics will be used to characterize all variables, and distributions of variables will be examined for outliers and normality. Then, transformations will be applied as appropriate. Internal consistency reliability estimates for multi-item scales of at least 0.7 will be considered acceptable. We will use an intent-to-treat approach; participants will be analyzed in their original randomized conditions regardless of the usages of the TICAA or follow-ups missed. The mechanism underlying missing data will be evaluated and appropriate imputation methodology will be implemented (e.g., missing at random and multiple imputation by chained equations).<sup>84</sup> All enrolled patients with at least one follow-up assessment will be included in outcome modeling, and the linear mixed effects modeling will take advantage of all available data. Baseline characteristics will be compared among patients with and without complete follow-up. To assess potential biases, a comparison of withdrawal rates will be included. <sup>84</sup> If the number of participants dropping out is small (10%) and the missing observations can be considered random, then the primary hypotheses will be tested using the complete observed data. If missing observations cannot be assumed to be random, more complex approaches (e.g., shared parameter models<sup>85</sup>) will be considered.

**Aim #1: Effects on Primary Outcomes.** Separate intent-to-treat general linear models<sup>86</sup> will be used to examine differences in continuous outcome measures by intervention group at each time point, adjusting for baseline outcome and any variables that demonstrate imbalances in preliminary analyses. Model assumptions will be assessed, and modifications will be implemented as necessary to improve model fit. Differences in continuous outcome measures over time will be examined using an intent-to-treat linear mixed-model growth curve analysis with SAS Proc Mixed.<sup>86</sup> Mixed models will be used in which all available data collected during follow-up is used.<sup>87,88</sup> Separate mixed effects regression models will be generated for each outcome measure. Both random slopes and intercepts will be modeled to represent the subject level deviation from the average, or fixed-effect, slope over time and intercept, respectively. Restricted maximum likelihood estimation will be used, and the most appropriate covariance structure will be examined. The outcomes will be analyzed as repeated observations of the dependent variables, with mean-centered baseline outcome scores serving as a covariate. Other predictors will include intervention group, time from baseline to follow-up, the interaction of group and time, and the interaction of baseline measures and time. Baseline outcome and group will be analyzed as time-independent covariates. Other demographic or treatment time-independent variables identified in preliminary analyses may be included as covariates. Main effects and higher order interaction terms will be examined. The Akaike information criterion will evaluate overall model fit and to select the best-fitting longitudinal change pattern.<sup>89</sup>

**Aim #2: Mediation of Intervention effects.** Sequential process random regression growth curve modeling<sup>90</sup> will be performed to explore the hypotheses that attitudes, self-efficacy, perceived barriers, and social influences, separately, mediate the relationship between intervention group and change over time in primary outcomes. Specifically, we will examine whether the women who receive the TICAA show more favorable changes on the mediators at post-intervention and the follow-up periods relative to pre-intervention than do those in the control group. Mediation analyses will be performed to examine whether there is statistical support for the view that the putative mediator variables actually mediate effects of the TICAA on participants' needs for

help, physical and psychological symptoms, and quality of life. Although various methods are appropriate for evaluating mediation in this setting, random regression growth curve modeling<sup>90</sup> was chosen as it prospectively and longitudinally tests the three criteria of mediation proposed by Baron and Kenny. <sup>91</sup> Modeling will rely on incorporating time varying [mediator] as a predictor of outcome in each sequential assessment. To test the mediation hypothesis, individual slope and intercept parameters will be estimated for each participant based on intervention, mediator, and outcome. The intercept parameters will be coded to represent the value of the linear growth trajectory for each participant at baseline. The sequential process, or lagged approach, will allow for stronger inference regarding causality. Model assumptions will be assessed, and transformations will be applied as necessary. A series of four regressions will be used to test each of the mediational chains according to the criteria specified by Baron and Kenny.<sup>91</sup> Significant decreases in outcome will be assessed using the Sobel test. <sup>92</sup>

**Aim #3: Moderation of Intervention Effects.** The moderating role of background and disease factors will be generated for each outcome. Intention-to-treat mixed-modeling procedures<sup>86</sup> as described above will be used to test and estimate differences in outcome across intervention groups and how moderators modify such differences. Accordingly, coefficient estimates for these measures by time represent the extent to which mediators affect slopes of change for outcome across time. Initial models will include all main effects and possible two- and three-way interactions between moderator, intervention group, and time. With respect to random effects, in addition to random intercepts, random slopes for time, moderator variables will be estimated to account for within-individual variability. As before, each model will control for baseline outcome values, which will be centered about the grand mean for all patients. Accordingly, intercepts represent the mean baseline outcome score across patients, adjusting for all other values included in the respective models.

- Training of study team

All research team members will complete CITI training before engaged in the study. Also, to eliminate contamination across interventionists and minimize risk of differential treatment delivery among different interventionists, the interventionists will be trained by the PI with the intervention protocol developed through PSs. The interventionists' first 5 messages through the social media sites and the chat function will be monitored and evaluated by the research team, and the team's feedback will be incorporated into their subsequent coaching/support. Also, the interventionists will learn methods of facilitating discussions without influencing participants and helping women to set goals and solve problems. Two culturally-matched RAs will be trained on the logistics for the participant recruitment, the online survey system, and the delivery of the online questionnaires. Team meetings will be held monthly to address problems, reinforce learning, and monitor progress. Retraining of the interventionists and RAs will be done every 18 months to prevent drift.

- Plans for Monitoring the Study for Safety

Since Data and Safety Monitoring Boards (DSMBs) are required only for phase III clinical trials (NOT-OD-00-038.html), we do not include a DSMB for this intervention study. For the proposed intervention study, we have the following data safety monitoring plan (DSMP). First, to manage and protect the data collected, only summary data will be openly accessible to funding agency or will appear in publications. Research participants will be informed that they are free to decline to answer any questions they do not wish to answer or to stop participating in the project at any time. When a participant withdraws from participation, the data that they have provided will be immediately removed. Also, the data will have no identifying information to link a subject to the data. The participants' records will be handled as confidentially as possible. Only the research team will have access to the study records. Only a serial ID number assigned by the researcher will be attached to the data, and the data will be stored in a locked file cabinet in a research office. No identity information, including IP addresses, will be attached to any of the individual or group data. Therefore, research participants will not be identifiable directly or through the identifying information linked to subjects. No individual identities will be used in any reports or publications that will result from this study. Additionally, as explained above, the Web site will be developed and maintained such that it conforms to the HIPAA standards and SANS/FBI recommendations. Finally, data in the servers will be daily monitored by Dr. Chee to ensure its safety and security. All the participants will be asked (before participating in the study) if they have a regular source of health care so that the researcher could refer them if there is an adverse event identified during the data collection process. If the participants do not have a regular source of health care, then the researcher will get on the web and find a clinic or health care center near the participants' locations that they can go to for emergency health care, if needed. During the data collection process, online records of the TICAA implementation will be monitored daily by a culturally matched RA under the supervision of Drs. Im, Mao, and Schapira, and any potential and actual adverse health problems will be identified through the monitoring process. In addition, the research team will meet regularly to monitor the research process, monitor the online records, monitor participant adherence, and address any issues that arise and consult as necessary with consultants.

- Confidentiality:

All e-mail/Internet communication between participants and the research team will be kept confidential by saving e-mails on the study team secure server with restricted access only to research team members. All e-mails received or sent by participants or the research team and other identity information will not be shared with others, and they will be on a firewall-protected computer to which only the research team can access. Also, at the completion of the study, the saved e-mails will be permanently destroyed to ensure confidentiality. In addition, as described earlier, e-mail addresses will be used only for reminders and participation compensation, and will be kept separate from other participant data. Furthermore, their email addresses will be accessed only by the research team, and the participants can communicate with other participants only through the social media sites (no email address will be disclosed to other participants).

As described above, the data that the participants will provide will not include any information linked to their identities except email addresses, and only research staff will have access to the data. E-mail addresses will be used only for the reminders and reimbursement. As explained above, at the completion of the study, the saved e-mails will be permanently destroyed to ensure confidentiality.

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