COVER SHEET:

Title of Study:

Nueva Vida Intervention for Latina Breast Cancer Survivors and Caregivers

NCT Number:
NCT02222337

Date of this document:
12/17/12

PCORI RESEARCH PLAN

RESEARCH STRATEGY

Part A: Background and Significance

A. 1. *Impact of the Condition on the Health of Individuals and Populations (Criterion 1)*

In the United States, 50.5 million people are of Hispanic/Latino origin.[25] The lifetime risk for cancer among individuals of Latino origin is striking: 1 in 2 for men and 1 in 3 for Latino women (hereafter "Latinas").[26] With these rates, approximately 8.5 million Latinas will develop cancer in their lifetime, with breast cancer as the most common cancer and cause of cancer death among Latinas.[26] Over 17,000 Latina women are expected to be diagnosed with breast cancer in 2012.[26] With growing numbers of Latina women diagnosed with and surviving breast cancer (hereafter "survivors," which includes women from the time of diagnosis onward),[27] attention to quality of life (QOL) after diagnosis has also increased.

Research evidence from our group and others and our experience as clinicians and service providers indicates that Latina breast cancer survivors have lower QOL compared to non-Latina survivors.[2,3,28,29] The disparity in QOL experienced by Latinas is clinically significant in terms of depression, pain, fatigue and strained spousal and family relationships.[1,30,31] Moreover, this symptom burden may contribute to work, financial problems and emotional strain among Latina survivors and their caregivers and families.[32]

Cancer caregivers for Latina breast cancer survivors include spouses, partners, adult children, other family members, friends and members of their faith communities.[6,10,33] Research with primarily non-Latino cancer caregivers indicates that they experience increased distress[34] and physical symptoms[9,34,35] compared to age- and gender-matched controls.[36] Indeed, the strain of caregiving for a cancer patient can have wide reaching effects, including missed days at work, reduced productivity[37] and impaired social functioning.[38] Moreover, physical health outcomes of caregivers of breast cancer patients are related to the patients' own depression and stress.[39] Although with notable exceptions,[6,10,33] few studies of cancer caregivers have explored the unique needs and outcomes in Latinos. Research to date has identified Mexican-American caregivers' lack of confidence and self-efficacy in their ability to cope with their survivors' illness, communication difficulties and concerns over management of the survivor's distress or depression.[6,10,33] We will build upon this prior research by including a heterogeneous Latino sample and testing an intervention developed to reflect the cultural values and preferences of Latino survivors and caregivers.[17] *Observations in the literature indicate a critical need for evaluation of patient-caregiver interventions to improve QOL in underserved groups like Latinos.*[34,40]

If successful, the proposed study could address several cross-cutting questions. *First*, study findings could have relevance for questions about how to best improve quality of life in other racial or ethnic minorities. For example, few studies describe the empirical evaluation of QOL interventions with African-American and Chinese-American breast cancer survivors.[41,42] Likewise, results from the proposed study could suggest potential avenues for the design of future interventions with racial or ethnic minority caregivers or address questions related to how to recruit diverse breast cancer survivors into interventions when delivered in community settings. *Second*, our study has implications for efforts to improve QOL of people with other chronic diseases that impact caregivers, such as diabetes ,[43] heart disease[44] or other types of cancer.[45,46] Specifically, future efforts could benefit from the proposed intervention's format, topics and/or emphasis on the dyadic relationship between the patient and caregiver. *Third*, our study will provide additional information about the best methods to assess patient-reported outcomes in a diverse sample of mono- and bilingual Latinos. We propose to measure QOL outcomes using the Patient-Reported Outcomes Measurement Information System

(PROMIS). We will administer PROMIS using a computerized-adaptive testing (CAT) delivered over the telephone with a trained interviewer.

A.2. *Innovation and Potential for Improvement Through Research (Criterion 2)*

A.2.1. Innovation. Our proposed research will compare an innovative patient-caregiver intervention to usual care among Latina breast cancer survivors and their caregivers. Importantly, our intervention was developed by Latina survivors and their service providers to specifically address survivor and caregiver needs. Our work is innovative for at least three key reasons.

First, our research will be among the first to evaluate a cancer patient-caregiver intervention with an ethnically diverse sample. We are aware of only one published intervention study involving Latina survivors and their caregivers. This intervention compared health education to health education plus counseling and was delivered primarily to individual dyads of Mexican-American breast cancer survivors and their caregivers. Conducted by telephone, both intervention arms led to improvements in QOL for survivors and caregivers.[6] To our knowledge, the proposed trial will be the only study to focus on Latinos from countries beyond Mexico. Evaluating an intervention with other Latino groups is important given the diversity within various Latino cultures.[47] Recent reviews of the cancer caregiving literature indicate a striking lack of research that includes caregivers from diverse ethnic, socioeconomic and cultural backgrounds.[34,40] ***Our study directly fills this gap.***

Second, our patient-caregiver intervention (PCI) is uniquely formatted to reflect the cultural preferences and values of Latina survivors and their spousal, family and friend caregivers.[15,17,48] The unique format involves twice monthly sessions in which the survivors and caregivers arrive together, separate into small groups (e.g., one room with survivors, one room with caregivers), and then meet together again at the end of the session to share food and discussion. This format of concurrent small group sessions is derived from an award-winning and empirically-proven program, *Mi Familia* (My Family), developed by Ms. Gloria Elliott (Consultant), a breast cancer survivor and mental health professional, and a colleague when they worked at La Clínica del Pueblo in Washington DC.[49,50] *Mi Familia* is a program to help Latino families cope with traumatic stress based on tenets from Cognitive Behavioral Therapy and Social Cognitive Theory.[51,52] Sessions are referred to as "workshops" (*talleres*) to reduce the cultural stigma against therapy and are viewed as a time for the family to come together to learn new skills and socialize with other families experiencing a similar situation. Ms. Elliott and her colleague then adapted *Mi Familia* for use with Latina breast cancer survivors and their caregivers (called the *Cuidando*/Caregiver program), referencing the work of Dr. Jacobs (Consultant).[53] Caregivers of Latina cancer survivors and in particular, Latino men, appeared to have significant difficulties openly sharing their thoughts and feelings in front of survivors. The program structure provided a perfect opportunity for caregivers to express their concerns without the fear and worry of upsetting the Latina survivor. This format and the content–teaching communication and coping skills–provide the caregivers with the information and techniques they need to best support themselves and the Latina survivor. ***This unique approach, developed by a Latina survivor based on empirical and theoretical evidence, will be formally tested for the first time as an intervention with ethnically and socioeconomically diverse cancer survivors and their caregivers.***[34,54]

Third, we will use an innovative approach to measure QOL outcomes through the Patient-Reported Outcomes Measurement Information System (PROMIS). PROMIS was initiated by the NIH in 2004 to develop standardized, valid, and precise measures of multiple domains for use in clinical research. Unlike traditional instruments, PROMIS has constructed "item banks" of a large number of items per domain that have undergone rigorous qualitative and quantitative testing.[55,56] By using computerized-adaptive testing technology, items are tailored to an individual's current level on a particular domain, resulting in lower respondent burden and more precision at the floor or ceiling of the trait.[57] We selected PROMIS to more precisely measure differences and longitudinal changes in the PCI and UC groups. We will use PROMIS items that have been tested in Spanish.[58] ***Use of PROMIS will allow us to compare our findings to other cancer and non-cancer cohorts, reduce participant burden, and more precisely estimate QOL outcomes.***

Innovation summary. The proposed study is innovative in our inclusion of a diverse and heterogeneous sample of Latina survivors and caregivers, evaluation of a unique intervention and assessment of QOL using

PROMIS. We will learn whether inclusion of a caregiver as part of a psychosocial intervention provides added-value to the usual services available to Latina breast cancer survivors and their caregivers.

A.2.2. Potential Improvement through Research. Based on our previous research findings, current practice patterns, input from diverse team perspectives, and the direct relevance our proposed intervention has for patients and caregivers, the proposed intervention is very likely to improve patient and caregiver outcomes. All members of multidisciplinary team have provided feedback and input on the proposed research, including: academic researchers, breast cancer survivors, caregivers, service providers, clinicians, community-based leaders and patient advocates. The patient advocate group from whom we elicited feedback also indicated the study outcomes and our team's community-academic partnership are very appealing to them (see Letters of Support). Our proposed work is a direct reflection of research priorities identified by the Institute of Medicine in their landmark report, "From Patient Care to Patient Survivor: Lost in Transition"[59] and the National Cancer Institute's monograph on "Patient-Centered Communication in Cancer Care."[30]

Impact of the Information to be Gained. The expected clinical benefit from the proposed study is that Latina survivors' and caregivers' QOL will be improved. We have powered the study to be able to detect a clinically-significant difference in QOL between the PCI intervention and usual care if one exists.[60] QOL and other patient-reported outcomes have direct links to survival and prognostic indicators.[4,5,61] Likewise, improvements in communication between survivors and caregivers may lead to less family and caregiver strain as suggested by research on dyadic coping in couples facing cancer.[62,63] Among non-English speaking Latinas, language and cultural barriers can influence treatment decision-making[18,20] and adherence to guideline-consistent follow-up care.[15,26] If successful, our intervention will improve QOL and promote better communication within Latino families facing cancer and between a Latina survivor and her physician. We will explore whether the intervention also impacts adherence to guideline-concurrent follow-up care among Latina cancer survivors.

If the PCI intervention does not improve QOL more than usual care, we will still have learned how to engage caregivers into existing support programs at community-based organizations. Regardless of the outcomes, we will also still learn how to administer state-of-the-art assessment for key patient-reported outcomes to a diverse sample of Latinos through our use of PROMIS. Finally, the organization of our community-academic partnership, communication strategies, and production and delivery of study products (protocols, reports, manuscripts) can serve as a model for other teams interested in bringing together multiple community organizations, stakeholder groups and academic researchers.

How Study Findings Will Help Patients, Caregivers and Clinicians Make Decisions. Study findings will help Latina breast cancer survivors and caregivers make decisions about the best options for improving QOL after the family faces a breast cancer diagnosis. Group interventions such as PCI may not appeal to everyone; however, if a Latina survivor is facing a choice of seeking individual or group support, with or without involving her caregiver, then evidence from the proposed study may be useful to her decision. Likewise, caregivers who are uncertain about how to best support their survivor will benefit from an empirically-evaluated intervention. Finally, clinicians involved in the treatment and follow-up care of Latino families facing cancer will be able to consult scientific evidence about the types of support programs that best improve QOL and other patient-centered outcomes. Such evidence may help some clinicians feel more confident in their referrals of women to support programs offered in the community.[64]

How Study Findings Will Help Stakeholders Make Decisions that will Impact Patient-Centered Outcomes. Our proposed study creates a team that includes diverse perspectives and brings together four strong community-based organizations to partner with academic researchers. Our four community partners [Gilda's Club New York City,[22] Latinas Contra Cancer,[24] Nueva Vida, Inc.[17] and Self-Help for Women with Breast or Ovarian Cancer (SHARE) / LatinaSHARE][23] all offer support services to Latina breast cancer patients and most of them offer programs for caregivers. For three organizations, most of these services involve separate programs for survivors and caregivers, and few caregivers of Latina survivors participate in the

programs. In contrast, one organization, Nueva Vida, currently offers the proposed PCI with its innovative format. Nueva Vida has observed specific benefits to both survivors and caregivers after participating in their patient-caregiver program. *These observations led Nueva Vida to ask Dr. Graves (PI) to partner on the present submission to formally evaluate the program.* Nueva Vida and the other three partners are interested in learning which strategies provide the most benefit to Latina survivors and their caregivers. Each day, the patient navigators, promotoras (health educators) and trained mental health professionals make recommendations to Latina survivors and their family members about different options for support. Study findings will provide evidence about whether inclusion of caregivers significantly improves patient-centered outcomes of QOL, communication and satisfaction with care. We will also explore the impact of the intervention on adherence to guideline-concurrent follow-up care for survivors. The evidence gained from the proposed study could impact the types of services offered by each of these organizations (and other organizations like them). If successful, ***study outcomes could to lead to use of an empirically-based intervention for the thousands of Latina survivors who receive services from our four partners.***

Prospects for Prompt Dissemination and Adoption of Findings into Practice. Our study team is excited about the potential benefits of PCI and prospects for dissemination of study findings. We have several strategies for dissemination of study findings that we will explore and discuss further over the course of the study (see Section 8, Project Plan and Time Table and the Stakeholder and Patient Engagement Plan in People and Places). Below we describe some of these options.

First, we will disseminate study findings to study participants and to other families facing cancer who are served by the four partner organizations. Together, our four partners provide services and information to over 18,000 people annually, of which over 8,000 are Latino. We will disseminate study results through each of the organization's websites, newsletters and other print materials. Likewise, Gilda's Club New York City will help our team share study results with other Clubhouses across the country (see Letter of Support).

Second, we plan to hold an annual Community Meeting in San Jose, CA to share results with study participants, stakeholders, researchers and other community leaders. We have budgeted for English/Spanish translation and interpretation services at this Community Meeting and all planned study Team Meetings.

Third, we will expand upon connections with local patient advocacy groups to disseminate study results. For example, the Georgetown Lombardi Breast Cancer Patient Advocacy Committee (GLBCPAC) has reviewed the proposed study, provided feedback and indicated support for helping to disseminate study results (see Letter of Support). Our Advisory Board Members also have connections and diverse perspectives we will seek, with representation of a medical oncologist, breast surgeon, Latina breast cancer survivor, scientifically-trained advocate and director of a community-agency and a caregiver to a Latina survivor.

Fourth, we will be able to use the experience, connections and committee memberships of study team members to disseminate results to other groups. Members of our team hold committee or advisory or editorial board positions at a number of national organizations, including the Well Spouse Association, AARP Caregiver Advisory Panel, National Latina Breast Cancer Network, *Cancer Today*, National Breast Cancer Coalition, Intercultural Cancer Council, Young Survivors Coalition on Diversity, Redes En Acción, Immigrant Leadership Forum, American Society of Clinical Oncology Clinical Guidelines Committee, Breast Cancer Advisory Board / Black Women's Health Imperative, National Coalition for Cancer Survivorship and the National Latino Hispanic Board of Advisors of The Lance Armstrong Foundation. We will brainstorm appropriate ways to share the study results with some or all of these groups during our Team Meetings and teleconferences.

Fifth, we will share study findings at the biennial National Latino Cancer Summit in 2014 (and again in 2016). Organized by Ysabel Duron of Latinas Contra Cancer, The Summit brings together lead researchers, service providers, community organizations, policy makers, clinicians, promotoras, patients and advocates to discuss current topics related to Latinos and cancer. The Summit has drawn over 750 attendees since 2008. Team

members from Latinas Contra Cancer and the other community-based organizations will take the lead on our conference submission and presentation.
Sixth, we will work through our study team members who have connections with the Cancer Support Community (CSC), an international non-profit with over 50 local affiliates and 100 satellite affiliates. Gilda's Club New York City is a CSC affiliate and has offered to guide our team in the best way to disseminate study results and discuss options for adoption of the findings into practice across the CSC network. Moreover, Dr. Barry Jacobs (Consultant) serves on the Cancer Caregiving Advisory Panel of the CSC and thus we expect to be able to share results through both internal (Dr. Jacobs) and external (affiliates) channels.

Finally, we will leverage institutional resources at Georgetown University Medical Center (GUMC) to help us identify and efficiently use additional methods of result dissemination. For example, GUMC is part of the Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS) funded through a National Institutes of Health Center for Translational Science Award. GHUCCTS resources include the Community Engagement and Research component, which will help the study team keep the DC community informed about ongoing research activities and results of completed projects. Likewise, GUMC recently established the Center of Excellence for Health Disparities in Our Nation's Capital (CEHD), also funded by the National Institutes of Health. The CEHD is part of the Georgetown Initiative to Reduce Health Disparities. Dr. Sheppard (Co-Investigator) is an Expert Member of this Initiative and will advise the study team on additional avenues of outreach, dissemination and timely methods for adoption of the intervention into practice.

Preliminary Studies. Our team includes the constituencies and expertise needed to reduce disparities in QOL experienced by Latina cancer survivors and caregivers. Below we outline our preliminary data and experience.

Interventions with Breast Cancer Survivors. We have significant experience evaluating QOL psychosocial interventions with cancer survivors,[14,65] with a particular emphasis on interventions with Latinas.[16,18] Dr. Graves (PI) led a study to compare an 8-week QOL intervention based on Social Cognitive Theory with expressive writing (F32CA97760). Dr. Nápoles (Consultant) adapted the intervention developed by Dr. Graves for use with Latina breast cancer survivors and is currently conducting a community-based participatory research randomized clinical trial (CBCR15BB-1300). Finally, Dr. Sheppard (Co-investigator) has conducted several interventions with breast cancer survivors. She piloted the first decision support intervention for Latinas to increase their self-efficacy for treatment decision-making and communication with providers.[18] Data suggest high acceptability of the intervention and improved communication outcomes among survivors.[18] Dr. Sheppard has also developed and tested interventions to improve patient-physician communication[66] and physical activity and nutrition (R21CA149996) among African American breast cancer survivors.

Quality of Life Outcomes in Latina Cancer Survivors. Drs. Graves, Jensen, Mandelblatt (GU), Mrs. Caicedo (Nueva Vida) and Ms. Jandorf (Consultant) examined the cultural and contextual factors related to QOL in Latina survivors. In a national cross-sectional sample, bilingual and bi-cultural staff conducted interviews with 264 diverse Latina breast cancer survivors. Latina survivors were 1-5 years post-diagnosis and reported a lower mean QOL score compared to other published reports of non-Latina survivors (M=105; SD=19.4 on the FACT-B).[67] Culturally-based feelings of breast cancer-related stigma and shame were consistently related to lower overall QOL and lower well-being in QOL subdomains. Social and medical contextual factors also were independently related to QOL; together the cultural and contextual factors uniquely accounted for 62% of the explained variance of QOL. [2]

Table 1. Nueva Vida's Partnerships with Academic Medical Centers
Latina Breast Cancer Survivors' Lived Experiences: Diagnosis, Treatment and Beyond [68]
Latina a Latina: Developing a Breast Cancer Decision Support Intervention [18]
Quality of Life among Immigrant Latina Breast Cancer Survivors: Realities of Culture and Enhancing Cancer Care [15]
Awareness of and Willingness to Participate in Cancer Clinical Trials among Immigrant Latinos [69]
Through the Lens of Culture: Predictors of Quality of Life Among Latina Breast Cancer Survivors[2]

Support Services for Latina Survivors and Families. Nueva Vida is an award-winning community-based organization that aims to provide support and improve QOL in Latina survivors using

evidence-based practices (see Table 1).[70] Nueva Vida provides a continuum of culturally-sensitive cancer support services for Latinas in Washington DC, Baltimore, MD and Richmond, VA. The only independent survivor-driven cancer care organization for Latinas in the area, Nueva Vida serves over 4,000 individuals and families, reaching countless more as a resource to regional and national healthcare partners.

Guided by the topics outlined by caregiving expert Dr. Jacobs (Consultant),[53] Ms. Elliott (Consultant) adapted the *Mi Familia* program to create Nueva Vida's *Cuidador* (Caregiver) program for Latina families experiencing breast cancer.[48-50] The Nueva Vida team has been offering the patient-caregiver intervention in the proposed format for 2 years to over 30 Latina survivor-caregiver dyads. Importantly, survivors and caregivers who attend Nueva Vida's *Cuidador* program reported positive changes in: family life (93%), relationship with one another (50%), work (72%), feeling better with self (100%), being more active (93%) and their spiritual life (100%). The proposed work will be the first formal evaluation of Nueva Vida's *Cuidador* intervention. Further, a RCT will allow us to test the intervention in other community settings in New York City, NY and San Jose, CA to include Latina survivors from multiple countries of origin (see Table 5).

Psychological Interventions with Latina Immigrants. Dr. Kaltman (Co-investigator) has led several studies to understand and improve psychological outcomes among Latina immigrants who have experienced trauma. Latina immigrants in the Washington DC area report high levels of both trauma and social isolation.[71] Among a sample of 101 Latinas, more than one third of the sample (36%) met presumptive criteria for depression, post-traumatic stress disorder, or generalized anxiety disorder. Latina immigrants also reported somatic symptoms involving fatigue, pain and headaches.[72] Based on her prior work,[73] Dr. Kaltman and her team developed a novel mental health intervention for low-income, trauma-exposed Latinas called *Mente Sana/Cuerpo Sano* (Healthy Mind/Healthy Body).[74] A pilot test with 28 Latina immigrants led to reduced levels of presumptive depression and post-traumatic stress disorder (PTSD; Table 2). The present intervention builds on Dr. Kaltman's experience providing mental health services to underserved Latina immigrants.

Table 2. Results from *Mente Sana/Cuerpo Sano* Pilot

	Baseline	Post-Intervention		% No longer meeting presumptive criteria post-intervention
Outcome	*Mean (SD)*	*Mean (SD)*	*p*	
Depression	15.1 (3.5)	7.9 (6.6)	.001	66.7%
PTSD	46.2 (11.8)	33.0 (13.0)	.001	42.3%

Community-Based Participatory Research (CBPR). Our team has long-standing experience partnering with communities to conduct research. For example, Ms. Jandorf (Consultant), serves as the Project Director of the community-based outreach efforts at Mount Sinai School of Medicine (MSSM) including the NCI-initiated East Harlem Partnership of Cancer Awareness (EHPCA), the Witness Project of Harlem and *Esperanza y Vida* (*EyV*). The EHPCA is a coalition of hospitals, community health centers, and community agencies with the common goal of increasing cancer awareness and preventive care in East Harlem.[75] The EHPCA acts as MSSM's community advisory board and helped researchers to increase minority involvement in all aspects of the cancer care continuum.[76-78] Two primary outreach efforts of the EHPCA are The Witness Project of Harlem and *Esperanza y Vida* (Hope and Life), which represent culturally-sensitive educational efforts that require strong collaboration with faith- and community-based organizations. The mission of these programs is to increase awareness, knowledge, screening adherence, and early detection behaviors in minority women (particularly African American and Latina women) to reduce the mortality and morbidity from breast and cervical cancer. Results from the *Esperanza y Vida* project with over 120 Latinas indicated barriers to cancer prevention and care in the Latina community.[79] This work led to existing partnerships between Ms. Jandorf, LatinaSHARE and Gilda's Club New York City, two of our current community partners.

The Latin American Cancer Research Coalition (LACRC; U01CA114593-05), co-led by Dr. Mandelblatt (Co-Investigator) with involvement from Drs. Sheppard[69,80-82] and Graves,[2,83] aimed to improve cancer prevention and control outcomes among Latinas in the Washington DC area. The collaboration between Nueva Vida and Georgetown University Medical Center (GUMC) began as part of the LACRC, with productive results.[2,15,18]

Dr. Nápoles (Consultant) currently leads the *Nuevo Amanecer* (New Dawn) project at the University of California, San Francisco, funded through the California Breast Cancer Research Program. The goal of this CBPR project is to culturally adapt and test a psychosocial health intervention for Latinas newly diagnosed with breast cancer. The original intervention for this project was developed by Dr. Graves.[65] Latinas Contra Cancer is actively participating in Dr. Nápoles's *Nuevo Amanecer* project and several Latinas Contra Cancer personnel are involved in that effort as trained compañeras (companion/friend). *Nuevo Amanecer* will be completed prior to study enrollment for the proposed project.

Cancer Screening and Risk Awareness among Latinas. Since 1998, Dr. Warren (Co-investigator), a medical oncologist, has led the *Celebremos la Vida* (Celebration of Life) Program at Lombardi Comprehensive Cancer Center (LCCC) at GUMC. This clinical service program, funded by the Prevent Cancer Foundation, has provided breast and cervical cancer screening for over 2000 Latino women.[84] In other work, Dr. Graves evaluated predictors of mammography among 448 Latinas at low-risk for breast cancer. The majority (81%) overestimated their breast cancer risk. Controlling for demographic, clinical, and perceived risk variables, only breast cancer knowledge predicted adherence to mammography recommendations.[83] Finally, Ms. Jandorf (Consultant) has evaluated awareness of breast cancer risk among Latinas at increased risk for breast cancer based on personal and family history. This work led to the development and formative evaluation of an educational DVD to inform at-risk Latinas about genetic counseling for the *BRCA1/2* genetic mutations.[19]

Use of PROMIS. Drs. Jensen, Sheppard and Mandelblatt (Co-investigators) are involved in a generalizability study of PROMIS domains across diverse racial, ethnic, and age-specific populations of cancer survivors using advanced psychometric techniques (U01AR057971-01; 3U01AR057971-02S1). Dr. Jensen has supervised survey development and implementation. The psychometric fundamentals behind PROMIS allow for a common scoring metric that is comparable across all test forms that use PROMIS items, regardless of administration (e.g., CAT or fixed form) and scored relative to a general U.S. population t-score metric (mean=50, SD=10). Of the 5,000 survivors, 1,000 will be Latino and 204 will be Latina breast cancer survivors. This work will allow us to easily compare the QOL outcomes in the proposed study to Latino- and non-Latino cancer survivors and the general population. Dr. Jensen is successfully implementing PROMIS CAT in a current study with a sample of patients with metastatic brain cancer. She also has experience using the PROMIS Assessment Center,[85] which is a NIH-funded online research management tool. This software allows for a distinct, study-specific website URL that accommodates PROMIS items as well as other measures. Importantly, the software has undergone extensive testing and evaluation to determine usability.[86]

A.3. Impact on Health Care Performance (Criterion 3). Our proposed intervention will impact health care performance in three ways. First, our study findings will contribute to the evidence base of the type and format of interventions that most improve patient-centered outcomes of QOL among Latina survivors and their caregivers. Use of empirically-supported interventions by community organizations, hospitals, clinics and other stakeholder groups can lead to efficiencies in care that yield improved outcomes. For example, if our study is successful, additional counselors or mental health providers could be trained to deliver the PCI intervention and both survivors and caregivers will benefit. We expect that PCI will also yield improvements in communication. Better communication between survivors and their healthcare providers can improve the survivors' experience in treatment decision making. For example, predominantly Spanish-language Latinas reported greater dissatisfaction with their treatment-decision making process than other survivors.[87] Language or cultural barriers between Latina survivors and their physicians also appear to contribute to treatment delays, receipt of different types of treatment[88] and possibly adherence to guideline-concurrent follow-up care.[15,26] Among breast cancer survivors, both younger age and greater mammography-related anxiety were associated with lower rates of surveillance mammography.[89] Notably, Latina survivors are often younger at the time of diagnosis[26] and may experience fears that impact on-going mammography.[15] ***If successful, our study will provide evidence for an intervention to reduce existing QOL disparities in Latinas and improve survivor-provider communication that can impact health care.***

Part B: Relevance to Patients (*Criterion 4*)

The proposed study has direct relevance to patients and their caregivers in response to two key questions in PCORI's definition of patient-centered outcomes research. First, our study will provide information related to the question, ***"Given my personal characteristics, conditions and preferences, what should I expect will happen to me?"*** Latina survivors will have the option to participate in a program that is expected to increase their QOL, improve their communication with their provider and with their caregiver, and improve their satisfaction with their cancer care. The PCI intervention will be delivered by trained, bilingual and bicultural interventionists. PCI was developed by Latina survivors and mental health professionals to provide culturally-competent care that respects Latino values and traditions. Caregivers will be able to expect a program that is also developed for their own needs and concerns.

Second, our study is designed to help Latina breast cancer survivors, caregivers and their clinical service providers make decisions about the type and format of support services. We will be able to provide direct evidence in response to the question, ***"What can I do to improve the outcomes that are most important to me?"*** We anticipate that PCI will be superior to usual care in terms of the patient-centered outcomes of QOL, communication and satisfaction with cancer care. Directed by the needs of patients, caregivers, providers, national guidelines and research agencies, we aim to reduce disparities in QOL outcomes among Latina survivors and caregivers by comparing a linguistically- and culturally-appropriate intervention to usual care.

Part C: Approach (Rigorous Research Methods) (*Criterion 5*)

C.1. Study Design. Research Question. The proposed study is designed to answer the question, "***Does an enhanced intervention improve QOL, communication, and satisfaction with care more than usual care among Latina breast cancer patients and their caregivers?"*** We propose to answer this question by focusing on strategies that align with the above patient-centered research questions. Specifically, Latina survivors, caregivers and providers may not be aware that different options exist to help teach them strategies to improve QOL, improve communication with caregivers and health-care providers, and enhance coping with the physical and emotional consequences of breast cancer diagnosis, treatment and follow-up care.[11]

Choice of Comparators. We will compare a patient-caregiver intervention (PCI) to usual care. We elected to compare PCI to usual care for several reasons. First, PCI is an intervention developed by and for Latina survivors. It is being successfully used at Nueva Vida, a community organization that provides care and support to Latinas with breast cancer in the Washington, DC metropolitan area (see Appendix A for sample materials). Second, no other organizations or clinics are currently using the PCI intervention. Third, no research to date has evaluated a patient and caregiver intervention in an ethnically diverse sample of cancer survivors and caregivers.[34] Fourth, our comparator of usual care is reasonable given that the other community organizations involved all provide support programs, navigation and educational initiatives for Latina survivors.[22-24] If PCI performs better than usual care at improving key patient-centered outcomes, then community organizations and other stakeholder groups can adopt PCI into practice. We will carefully monitor adherence to both PCI and attendance at any services available through usual care. We will include both intent-to-treat and "per protocol" analyses to investigate the impact of session attendance on study outcomes (see Analytic Methods). Below we describe the intervention and usual care.

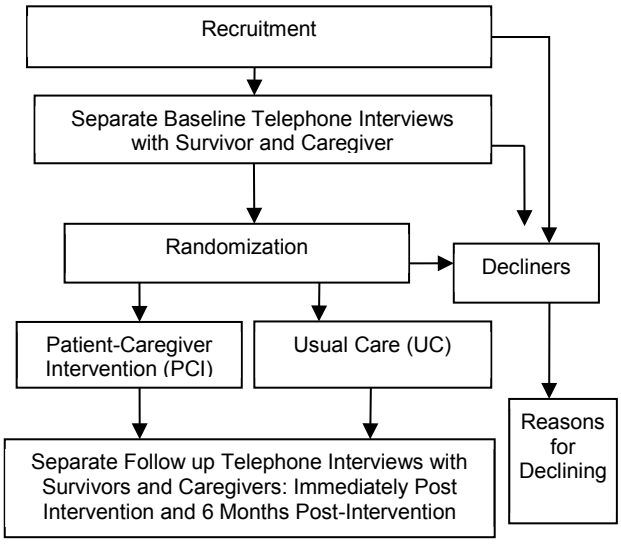
Refinement of Intervention Materials. We will refine the PCI intervention protocols/manuals based on in-depth interviews with 10 Latina survivors-caregiver dyads (see Appendix B). The interviews will allow us to refine the intervention for Latinas from different geographic regions (DC, NY or CA) and from different countries of origin (see Table 5). PCI is based on our current materials (Appendix A), experience,[16-18,53,65,90,91] formative work and our conceptual models.[12,14,62] Team and advisory board members will provide further input on ways to refine PCI, reflecting perspectives from patients, caregivers, providers (clinical and counseling psychology, medical oncology, breast surgery, internal medicine, social work), researchers (health services, public health, disparities) and stakeholders (patient advocates, community partners).

Patient-Caregiver Intervention (PCI). The PCI intervention will be modeled on the current *Cuidador* program at Nueva Vida. In in-depth interviews, we will elicit participants' feedback on the existing session topics and format (see Table 3; Appendix B). The psychosocial format of PCI is as follows: at the beginning of each new intervention group, the trained interventionists will introduce themselves to the overall group of survivors and caregivers, explaining that the purpose is to come together and learn new skills and ways of talking with each other. The facilitators will indicate that at each session, the survivors and caregivers will go into different rooms to discuss the same topic–a format that will allow them each to express their thoughts and feelings without inhibitions or concerns over how their survivor or their caregiver might respond. The specific eight topics for each wave of PCI participants will be determined from the larger list of possible topics. This approach has been used successfully in the current *Cuidador* program and reflects strategies to engage and involve participants in the intervention.[92] We will track topics selected by each group to determine if survivors in different geographic regions opt for different topics. The separate survivor and caregiver groups will come back together at the end of each session for refreshments, socializing and a brief discussion of the day's topic. Sharing of food and gathering together at the end of each session is important to *personalismo* (sense of connection) among Latinos. The PCI intervention will last 8 sessions, with sessions held twice a month for 4 months. Each session will be 2 hours in duration. The timing of the intervention was determined based on Nueva Vida's experience working with Latina survivors and their families. Weekly sessions are too frequent and attendance is lower (Personal Communication September 19, 2012, Claudia Campos, Nueva Vida Cuidador facilitator), while monthly sessions can lose continuity. The content will be delivered by the trained interventionists. An example of the communication session content is in Appendix A. The intervention will involve behavioral strategies (goal-setting, self-monitoring, role-playing, skills-practice, feedback, homework); communication strategies (expression of feelings, monitoring of responses, modeling effective communication skills), emotional management (cognitive restructuring, recognition of negative thoughts, interdependence of emotional responses) and stress management (relaxation techniques, engaging in pleasant activities together).

Table 3. Current Patient-Caregiver Intervention (PCI) Topics
1. Impact of Cancer in the Family
2. Stress Management
3. Anger Management
4. Improving Communication: Family, Friends, Providers
5. Intimacy after Cancer: Emotional and Sexual
6. Spirituality and Cancer
7. Balancing Emotional and Physical Needs
8. Role Changes
9. End of Life Issues (Putting our Lives in Order)
10. Understanding Distress
11. Including Others in Helping Caregivers
12. Side Effects from Cancer Treatment

Usual Care (UC). UC will involve any current support services offered by the partnering community organizations including but not limited to patient navigation, support groups (held separately for survivors and caregivers), educational workshops, social activities, and family-based activities (e.g., Gilda's Club New York City has facilitated family programs, see Letter of Support). Importantly, the UC services are also delivered with respect to survivors' and caregivers' needs, preferences, language and cultural values. Caregivers within the dyads randomized to UC will not necessarily attend any support services unless they choose to do so on their own. Of note, caregivers assigned by chance to UC will complete assessments at the same time points as their survivor. We will time the assessments for survivors and caregivers in UC to correspond to the assessment time points of those assigned to PCI (baseline, immediately post-intervention; 6-months post intervention). Survivors or caregivers interested in attending the combined patient-caregiver intervention will be given the option

Figure 1. Flow for Phase II RCT of PCI vs. UC

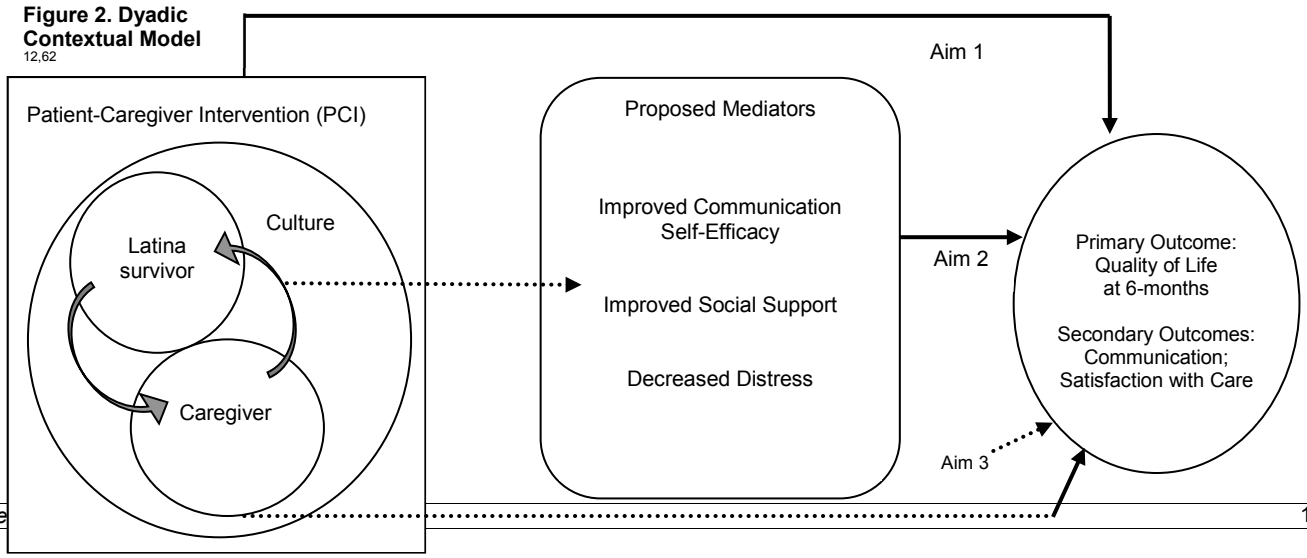


to do so after the final assessment at 6-months.

Choice of Study Design. We propose a randomized controlled trial (RCT) comparing a patient-caregiver intervention (PCI) to usual care (UC). Participants will be 100 Latina breast cancer survivors and 100 caregivers (N=200; 100 dyads). Survivors will be eligible regardless of time since diagnosis or stage of breast cancer. Caregivers will be a primary support person identified by the survivor. We will recruit Latina breast cancer survivors and their primary caregivers from our four partner organizations (Gilda's Club New York City, Latinas Contra Cancer, LatinaSHARE and Nueva Vida). We will use a mixed-methods approach in two research phases. First, we will complete individual qualitative interviews with 10 patient-caregiver dyads (n=4 dyads from NY, n=4 from CA, and n=2 dyads from Washington DC) to refine the intervention. This refinement will allow for any adjustments needed due to differences in the Latino populations of the different geographic regions and/or countries-of-origin. The intervention will be further revised following the team feedback at our initial meeting and during initial conference calls. Next, we will conduct a RCT to compare PCI to UC with QOL measured by PROMIS as the primary outcome (see Figure 1). After a baseline telephone interview completed separately by the survivor and her identified caregiver, Latina and survivor dyads will be randomized to PCI or UC. PCI participants (both the survivor and the caregiver) will attend eight 2-hour intervention sessions held twice a month at one of the four partner organizations. Intervention sessions (described as workshops or *talleres*) will be led by experienced interventionists who have attended a 2-day in-person training. Training all interventionists together will enhance fidelity[93] (see Appendix C). Each PCI session will begin with the survivor and caregiver going into different rooms to form separate small groups of Latina survivors and small groups of caregivers. Caregiver groups will involve both men (e.g., spouses, partners, friends) and women (e.g., sisters, adult daughters, friends). Nueva Vida has successfully led mixed-sex caregiver groups for 2 years. At the end of each session, the survivor and caregiver groups will come together to share food and conversation.

Conceptual Model. In addition to the empirical evidence of the key role of culture in health and psychosocial outcomes among Latina survivors and their family members,[3,6,11,12] our proposed work is guided by two conceptual models. First, our work is influenced by the Contextual Model of Health-Related QOL.[12] This model specifies individual (e.g., disease characteristics) cultural (*familismo, personalismo*, social support, acculturation) and contextual influences (dyadic relationships, communication with physicians, satisfaction with care) as important determinants of QOL. The dyadic component of our model is derived from Berg and Upchurch;[62] dyadic communication, perceived stress and communication reciprocally influence outcomes for both the patient and their partner or caregiver (Figure 2). Our proposed work is also in direct response to identified needs of Latina survivors, observations by a community organization that provides direct service and support to Latina survivors and recent calls in the cancer and caregiving literatures to involve family and incorporate cultural beliefs and values into interventions for cancer survivors and their caregivers.[34,40]

Figure 2. Dyadic Contextual Model
12,62



Second, our intervention strategy is informed by Social Cognitive Theory.[13] A key construct in Social Cognitive Theory is self-efficacy, or one's confidence in his or her ability to engage in specific behaviors. The intervention is designed to increase self-efficacy in communication between a survivor and her caregiver. The intervention is also designed to alleviate distress in terms of normalizing the experiences of or difficulties with coping as a survivor or caregiver, providing support, giving positive feedback and modeling acceptance.[51] Distress is changed through cognitive restructuring.[52] We hypothesize that changes in QOL will be due to improved communication self-efficacy, improved social support and decreased distress in PCI vs. UC participants.

Table 4. Study Measures	Base-line	T1	T2
Background Factors			
Sociodemographics	X		
Medical History	X	X	X
Cultural Factors			
Breast Cancer Stigma	X	X	X
Religious Coping, *Familismo*	X	X	X
Acculturation	X	X	X
Medical-Contextual Factors			
Communication with Providers	X	X	X
Medical Mistrust	X	X	X
Mediating Variables			
Communication Self-efficacy	X	X	X
Social Support	X	X	X
Distress	X	X	X
Outcome Measure			
QOL (Using PROMIS)	X	X	X
Secondary Outcomes			
Communication (Provider)	X	X	X
Communication (Caregiver)	X	X	X
Satisfaction with Care	X	X	X
Adherence to Guideline-Concurrent Care	X	X	X
Dyadic Factors			
Dyadic Support	X	X	X
Dyadic Perspective	X	X	X
Social Constraints	X	X	X
Process Variables			
Intervention Satisfaction		X	X
Fidelity Measures		X	X
T1 = Immediately Post Intervention; T2 = 6-Months Post Intervention Completion			

Choice of Outcomes. We selected outcomes that are patient-centered, clinically meaningful and relevant to stakeholder decision-makers. Foremost, our primary outcome variable is QOL, an outcome valuable to Latina survivors,[15] caregivers,[34] clinicians, service-providers and stakeholders (see Letters of Support). Secondary outcomes include communication (survivor-caregiver and survivor-provider), satisfaction with cancer care and adherence to guideline concurrent follow-up care. Most of the instruments we will use are validated in Spanish. For scales not previously translated/tested in Spanish, we will follow procedures of Dr. Nápoles, who has expertise in the translation and cultural adaptation of survey instruments. Missing data will be minimized as trained, bilingual and bicultural research personnel will administer assessments by telephone**.** Of note, study assessments will be completed by GUMC research personnel not associated with the delivery of the intervention. We will make every effort to blind the assessor to the participants' randomization assignment.

Background Factors. (a) **Sociodemographics** include sex, age, marital and insurance status, race, education, income. (b) **Medical history** includes history of co-morbidities in both the survivor and the caregiver. We will also assess whether participants (survivor or caregiver) have provided care to another ill person.

Cultural Factors. (a) **Breast cancer stigma** will be measured using eight 5-point Likert scale items from the stigma subscale of the Body Image after Breast Cancer Questionnaire.[94] We have translated this subscale into Spanish (α=0.83).[2] (b) We will measure **religious coping** with the Religious Coping Scale.[95] (c) ***Familismo*** will be assessed with the 5-item Familism Scale.[96] Items are rated on a 10-point Likert scale and capture concepts such as family support and familial interconnectedness. (d) **Acculturation** will be measured with the Short-Acculturation Scale[97] including language use, media preferences and ethnic social relations (α=.90).[2]

Medical-Contextual Factors. (a) (b) **Medical mistrust** will be measured by the validated 12-item scale by Thompson and co-authored by Jandorf.[78] **Mediators.** (a) **Communication self-efficacy** will be measured with the communication subscale of the Cancer Behavior Inventory (CBI).[98] The CBI is a valid and reliable scale and has been translated into Spanish. We have also developed a 5-item dyadic communication self-efficacy scale (see Appendix D). (b) **Caregiver self-efficacy** will be assessed with the 21-item Caregiver

Inventory.[99] This scale has been validated in Spanish. (c) **Social support** will be measured with the 8-item Duke-UNC Functional Social Support Questionnaire,[100] which we have administered in Spanish with good reliability (α=0.87).[2] (d) **Distress** will be measured with the 12-item Brief Symptom Inventory.[101]

Outcome Variable. QOL will be measured with PROMIS (see Appendix D for sample items). PROMIS was initiated to develop standardized, valid, and precise measures of QOL for use in clinical research using modern measurement theory (item response theory).[57] Compared to traditional measures developed based on classical test theory (e.g., the SF-36), PROMIS item banks administered using CAT provide a more precise measure of QOL in both the floor and ceiling of the measure.[102-105] Thus, chronically ill patients with severely limited functioning are asked appropriate questions (e.g., are you able to get in and out of bed?) while young healthy patients are asked different items (e.g., are you able to run or jog for 1 mile?). Because all items come from the same PROMIS item bank, scores from different PROMIS measures that contain different items are able to be compared or combined together. For each QOL domain, PROMIS measures have been validated against existing QOL instruments used in the field, and PROMIS has either equivalent or more precise measurement of a person's level of QOL depending on where the person is located on the continuum.[105] The PROMIS domains we will use to assess QOL are: Global Health: Summary scores of physical, mental, general health; Physical Health: physical function; Mental Health (individual domains): anxiety, depression, anger. Social Health: satisfaction with social activities, social role, sexual function and illness impact measures (e.g., days of missed work). The number of items on each domain varies with CAT. Short-forms for each domain range from 4 to 20 items. PROMIS item banks for these domains have been extensively developed and tested[55,57] and have shown high reliability and validity in the general U.S. population and cancer-specific groups.[106] Differences of 0.3 to 0.5 standard deviation units or greater indicate clinical significance.[60,107]

Secondary Outcomes. (a) **Communication with Providers** will be measured with a validated 15-item measure.[108] Participants rate providers from poor to excellent with a sample item as "Treated me with respect." Communication with caregivers will be measured through several dyadic-based measures. (b) **Satisfaction with care** will be measured with 3 reliable items used by Dr. Nápoles in her prior work. [109] Finally, (c) **Adherence to guideline-concurrent follow-up care** will be based on following care guidelines of the American Society of Clinical Oncology [110] and measured using self-report items as done in prior work. [111]

Dyadic Factors. (a) **Dyadic support** will be measured with the 5-item scale by Northouse[112,113] which assesses the perceived support received by each member of the patient-caregiver dyad. (b) **Dyadic perspective**, meaning considering another's point of view about a specific topic like breast cancer, will be assessed with a modified version of the Thinking Beyond Oneself scale.[114] This scale has been used in dyadic cancer control research.[63] (c) **Social constraints** will be measured with the 5-item Social Constraints Scale.[115,116] We have used a Spanish translation of this scale and obtained good internal consistency.[2]

Process Variables. (a) **Satisfaction.** We will assess satisfaction with PCI and UC. (b) **Intervention fidelity.** We will measure adherence to intervention protocols, participants' engagement (attendance, participation), exposure to intervention content, quality of intervention delivery and differentiation between PCI and UC arms.[117,118] Staff will complete session contact logs and evaluation forms.[118]

C.2. Analytic Methods

Study Population. Inclusion/Exclusion Criteria. Latina breast cancer survivors will be eligible for this study if they: 1) self-identify as Latina, 2) speak English or Spanish and 3) can identify at least one primary, adult caregiver. Caregivers of Latina breast cancer survivors will be eligible if they are aged 21 to 80 years old and speak English or Spanish. Caregivers can be any adult identified by the survivor as providing care (e.g., spouse, adult child, friend). If a survivor has more than one primary caregiver, only one will be recruited to participate. We will recruit participants from our four sites. Area hospitals (St. Luke's Hospital; Doctors Community Hospital) with diverse Latino populations will refer eligible participants. Exclusion criteria are (a) inability to understand spoken English and/or Spanish or (b) cognitive impairment that precludes informed consent (determined by the PIs or Co-Investigators who are mental health professionals). We expect the survivors who enroll in the study to be similar to the survivors who are eligible for services across the four

community partner sites As such, ***we anticipate that our findings will be generalizable to the 8,000+ Latino families who receive care/support through our community partners.***

Anticipated Accrual. Our four sites collectively see about 300 newly diagnosed Latina breast cancer survivors each year (Table 5). From our prior recruitment efforts of Latinas, we conservatively estimate a minimum of 40% per year (n=125) will be eligible for the present study.

Table 5. Estimated Number of People Served.	Nueva Vida, Inc.	Latinas Contra Cancer	SHARE/ Latina Share	Gilda's Club NYC	Totals
Annual # of cancer survivors or family members served[a]	4,000	1,000	6,000	7,300	18,300
Annual # of Latino survivors or family members served[a]	4,000	1,000	2,000	1,200	8,200
Annual # Latina breast cancer survivors served	230	70	215	300	815
Annual # newly diagnosed Latina breast cancer survivors	70	50	80	100	300
Estimated Distribution of Countries-of-Origin among Latinos served	DC Site	CA Site	NY Sites		Estimated Study Distribution
% South American	27%	10%	11%		14%
% Central American[b]	57%	1%	5%		18%
%Dominican Republic	1%	1%	15%		8%
% Puerto Rican	1%	8%	21%		12%
% Caribbean / Other	6%	7%	9%		8%
% Mexican	6%	68%	27%		32%
% United States	2%	5%	11%		8%

[a]Through in-person, print or online support or educational programs.
[b]Central American other than Mexican

Ascertainment and Enrollment: Interviews. Eligible Latina survivors and caregivers will be recruited from our four sites or referred by a collaborating hospital or clinic. Contacts at each site will help identify eligible Latina survivors and will mail a study flyer inviting them and a primary caregiver to be involved in an in-depth interview. We will also use in-person recruitment to talk with survivors and caregivers at the four sites (e.g., at the time of patient navigation). If a survivor and/or caregiver is interested, a team member will follow up with further information about the study to determine eligibility and obtain consent from both individuals in the dyad.

Ascertainment, Enrollment and Retention: RCT. With over 2 years of enrollment into the RCT, we anticipate a total of 750 Latina survivor-caregiver dyads identified at the four sites with a minimum of 300 eligible dyads. We will establish procedures to identify eligible women by having the Project Director/Project Manager (PD/PM) at each site develop an eligibility checklist for their use. The PD at GUMC will coordinate this process across sites to ensure consistency. The PD/PM will check in weekly with the PD at GUMC to provide names of women who provided permission for the team to contact them. We will recruit caregivers through Latina survivors, a strategy that has been very successful at Nueva Vida. We will enroll 125 dyads. We have retained over 80% of Latina survivors in prior work.[25] We thus expect to retain 100 survivor-caregiver dyads at 6-months. We will discuss strategies to promote retention through teleconferences and annual meetings. We will customize strategies to each site.

Interventionist Training. Our team has experience conducting interventionist training for psychosocial interventions with breast cancer patients[65] and specifically Latina breast cancer patients.[16,18] Building on these skills, investigators will conduct a 2-day in-person training for the PCI interventionists. Training will involve a study overview and in-depth discussion of the intervention manual, topics for each session, therapeutic approaches and talking points to use during each session. Interventionist training will occur in person (DC and CA interventionists will travel to New York). We will have refresher interventionist training at our annual meetings to prevent drift.[93] We will also review intervention fidelity logs during weekly team teleconferences. Study investigators and consultants have trained interventionists from diverse backgrounds.[16,18,66,76]

Implementation. Baseline Interview. After study enrollment and consent, we will call survivor and caregiver participants to schedule separate 30-minute baseline telephone interviews. If we have not received signed consent documents at that time, we will describe the study again and answer questions. If the participant agrees, we will obtain verbal consent to conduct the interview. Participants will not be randomized until after baseline completion by each member of the dyad. Interviews will be conducted by a trained research assistant

at GUMC using internet-based secure data entry screens through the PROMIS Assessment Center. The Assessment Center provides support services to investigator-initiated surveys and use of PROMIS domains [85,86] delivered through computerized-adaptive testing. Guided by our conceptual model[12] (see Figure 2) we will assess background factors, cultural factors, medical-contextual factors, mediating variables, QOL outcomes, secondary outcomes and dyadic factors (see Table 4; Appendix D). We have experience with similar interviews. We will minimize interviewer bias with: 1) intensive training (e.g., mock interviews, standardized Q&A), 2) on-going interview monitoring by the PD, and 3) interview completion before randomization. Participants will receive a $10 gift card.

Randomization. After the baseline, we will randomize participants to PCI or UC via computer by the method of permuted blocks with blocks of size four. We will stratify randomization by location (DC, NY, CA). The GUMC PD will help guide each site PD/PM on accessing/using the web-based randomization database. Randomization is expected to balance key demographic factors such as age, time since diagnosis and survivors' stage of disease between the PCI and UC arms. We will carefully examine these factors in analyses and control any variables as appropriate.

RCT Implementation. Following randomization, survivor-caregiver dyads will begin either the PCI or proceed with UC. PCI sessions will be held at one of the four community partner sites and led by the trained bilingual and bi-cultural interventionists. Interventionists will work with the PD in DC to track intervention delivery process measures and participant attendance. We will use rolling recruitment and begin new groups as we enroll participants. Groups will consist of approximately 10 survivor-caregiver dyads each (n=20 in each PCI wave; n=10 in each PI wave). Groups will be closed such that newly enrolled participants will wait to begin a group until ~10 new dyads are identified.

Post-intervention and 6-month Follow-Up Interviews. Follow-up interviews assess QOL, secondary outcomes, proposed mediating variables (communication self-efficacy, social support, distress), cultural, contextual and dyadic factors (Table 4). We also will assess intervention process. Follow-up interviews will be 25 minutes and administered by telephone and conducted by the bilingual RA using internet-based data entry screens through the PROMIS Assessment Center. Participants will receive $10 for each completed interview.

Data Analyses. Aim 1. *To evaluate the impact of the PCI intervention on Latina survivors' and caregivers' QOL.* **H_1**: Survivors and caregivers in PCI will report higher QOL compared to those assigned to UC. Aim 1 analyses will be performed separately for the Latina survivors and carriers. With 50 Latina survivors (and caregivers) per arm we will have 84% power to detect a clinically significant difference in QOL of 6 points (0.6 SD on PROMIS QOL measures) at a significance level of 0.05. Changes of PROMIS of 5 points or more are clinically significant.[60] We will use a mixed effects model to compare the two arms with respect to QOL immediately post intervention and at 6-months, adjusting for statistically significant (at the 0.10 level) predictors of QOL identified in bivariate analyses. In addition to this intent-to-treat analysis, we will perform a "per protocol" comparison of intervention completers vs. non-completers (defined as attending fewer than five sessions). We will use a mixed effects model to compare these groups on QOL immediately post intervention and at 6-months, controlling for potential confounders associated with both intervention completion and QOL in bivariate analyses. As we expect the sample of Latina survivors and their caregivers in the present study to be representative of the over 8,000 individuals who seek services or information from the community organizations involved in the study, our findings should generalize to thousands of Latina women in the Washington DC, New York City and San Jose, CA areas. For the survivors we will also explore whether geographic region (DC, NY or CA), nationality (U.S. born vs. immigrant) or region of origin (e.g., Central America, South American) modifies the effect of the intervention on QOL. We will also explore whether caregiver gender impacts the effect of the intervention on QOL.

Aim 2. *To identify mediators of the PCI intervention on QOL.* **H_2**: Consistent with our experience and theoretical models, changes in QOL will be due to improved communication self-efficacy, improved social support and decreased distress among PCI participants vs. UC participants. Aim 2 analyses will be performed separately for the Latina survivors and caregivers. We will use the product of coefficients method to assess

mediation effects at 6-months.[119] We will use linear regression models to estimate the coefficients relating each mediating variable (self-efficacy, social support, and distress) to QOL at 6-months, and also the coefficients relating the intervention to each mediating variable. We will calculate the mediated effects as the products of corresponding coefficients and we will construct 95% confidence intervals according to the methods described by MacKinnon et al.[119] With 50 subjects per arm we will have 80% power to detect mediation effects of moderate size (with coefficient parameters of 0.39 or more) for each mediator.[119]

Aim 3. To evaluate the impact of the PCI intervention on Latina survivors' satisfaction with their cancer care. **H_3**: Survivors in PCI will report greater satisfaction with their cancer care compared to UC participants. With 50 Latina survivors per arm we will have 96% power to detect a clinically significant difference in satisfaction with care of 8 points (0.75 SD given estimated SD of 12)[120] at a significance level of 0.05. We will use a mixed effects model to compare the two arms with respect to satisfaction with care immediately post intervention and at 6-months, adjusting for statistically significant (at the 0.10 level) predictors of satisfaction with care identified in bivariate analyses. We will again explore whether the effect of the intervention on satisfaction with care is different for sub-groups of participants (e.g., whether the impact of PCI on satisfaction with care differs by geographic region (e.g., NY,CA) or region of origin (e.g., Central America, South American).

Exploratory Aim: To explore the impact of the PCI intervention on Latina survivors' adherence to guideline-concurrent care and surveillance. Given the exploratory nature of this aim no formal power calculation was performed. We will use logistic regression models to compare the two arms with respect to the binary outcomes of adherence to guideline-concurrent care (hormonal therapy; chemotherapy) and surveillance (mammogram within 12 months), controlling for the statistically significant (at the 0.05 level) covariates identified in bivariate analyses. We will also perform "per protocol" analyses of completers vs. non-completers similar to those described in Aim 1.

Avoidance of Bias: Study Limitations and Strengths. The proposed study has the following limitations: 1) Representation of only three geographic regions (New York, CA and Washington DC); this concern is mitigated by the diversity of the Latino populations at these sites. 2) Issues of mixed gender caregiver groups. We will explore caregiver gender as a covariate in our analyses. 3) Self-report of follow-up medical care. We will use established and validated measures from national surveys. 4) Use of incentives to enhance session attendance. We opted to include modest incentives to indicate our appreciation of participant's involvement in this research endeavor. Strengths include: 1) Test of an innovative, culturally-relevant intervention, 2) Inclusion of diverse and predominantly immigrant and monolingual Latino sample, 3) Involvement of a multi-disciplinary team through strong community-academic partnerships, 4) Use of PROMIS to measure QOL, 5) Attention to the reduction of bias through a) on-site interventionist training, b) different personnel to conduct intervention delivery and outcome assessment, c) efforts to blind outcome assessors to study assignment, d) use of strategies to promote intervention fidelity (see Appendix C), and e) prior and on-going engagement of patients, caregivers and key stakeholders in the development of the study questions, outcomes and implementation.

Part D: Inclusiveness of Different Populations (*Criterion 6*). Our study includes a diverse population of Latina breast cancer survivors and their caregivers. Survivors are eligible regardless of their stage of breast cancer, the amount of time since their diagnosis, treatment received, or prior use of support services. We elected to include survivors ages 18 and older years old as breast cancer is not diagnosed in women under age 18. Caregivers can be of any race, ethnicity, or gender. We anticipate that most caregivers will be of Latino/a ethnicity. Caregivers also need to be over age 18 as the needs and experiences of younger caregivers likely differ from that of adult caregivers. We elected to focus the intervention on Latina survivors and caregivers for several reasons. First, our community partners all serve Latina women diagnosed with breast cancer and all have reported the need for the proposed intervention that aims to improve QOL for both survivors and caregivers. Second, breast cancer is the most common cancer diagnosed in Latina women. Third, Latina survivors are underrepresented in research on interventions to improve quality of life. Fourth, caregivers of any race or ethnicity are underrepresented in intervention research that focuses on QOL and uses our unique approach of concurrent yet separately held groups. Importantly, we expect that our findings will be relevant to cancer survivors from other racial and ethnic backgrounds. We also expect that our findings

will generalize to the over 8,000 Latino families served by our partner organizations. Our team has overcome barriers to recruiting caregivers into Cuidador program at Nueva Vida, by encouraging the survivors to invite their caregivers themselves. The intervention sessions will be described as workshops or *talleres*. This approach has been extremely successful. In addition, the delivery of the intervention in known community-based organizations reduces the sense of mistrust.[18] Study interventionists will be bi-lingual and bi-cultural, further reducing barriers to participation.

REPLICATION AND REPRODUCIBILITY OF RESEARCH AND DATA SHARING PLAN

Replication of Research Findings

Our team will prepare a complete and final study protocol within the first 12 months of the study. This protocol will include descriptions of the:

1. Study population, including expected demographics (age, ethnicity, country of origin, gender, stage of disease, time since diagnosis). We will clearly define study eligibility and exclusion criteria.
2. Primary and secondary hypotheses to be tested. We anticipate the overall study aims and hypotheses will remain the same, although we are open to feedback and revisions based on our initial team meeting.
3. Sources and methods of measuring intervention and usual care exposure. We will describe how we will track intervention attendance and uptake of services through usual care. Study team members will use a central study database so that participant tracking is consistent across study sites.
4. Outcomes and co-variates to be tested. We have developed a draft of our baseline assessment measure that includes most (although not all) items we propose to measure, including our primary outcome of QOL. We will provide the study survey in print form and/or provide access to the PROMIS Assessment Center study specific website. We will create data codebooks and clearly indicate how all data is labeled and coded.
5. Coding instructions for all study variables will be provided.
6. Qualitative interview guide. We have included a draft of our interview guide in the appendix. We will provide the final and complete interview guide.
7. Analysis plan. We will create a written document of our planned analyses. This plan will also highlight the roles and contributions of each study team member to expected study deliverables.

We will register our RCT at www.Clinicaltrials.gov prior to enrollment in the RCT.

Although not required (given a budget less than $500,000 in direct costs per project year), we will be prepared to share study data following the approval of a Data Sharing Plan by all study team members. Below we provide a draft of this plan.

Pending the final approval and review of the study team, we will make de-identified data available by request to investigators not associated with the study team. Priority for sharing of data will be given to junior faculty and/or faculty interested in questions related to patient-centered outcomes or interventions with Latino families facing cancer. We see this study as an important resource for guiding community-academic partnerships to guide questions relevant to the communities being studied. We will develop a formal data request process. All Site PIs and the GUMC PI must agree and approve the data request process. Any requests for data from non-study investigators will be reviewed by the GUMC and Site PIs and Advisory Board Members to ensure that it does not conflict with planned analyses, is otherwise respectful of the study participants, and complies with all relevant IRB and HIPAA regulations. When approved, we will make study data available to other investigators under appropriate data sharing agreements that ensure that the data will be used only for research purposes, that any individual participant's de-identified data will not be disseminated, that the data will not be used to identify an individual participant, that data will be protected under appropriate security measures including encryption and password protection, and that the data will be destroyed or returned to us upon completion of relevant analyses. If appropriate, we will also determine whether at least one study investigator should be involved scientifically in any projects that result from data sharing requests. As noted, all of these procedures and data-sharing plans, requests and approvals will go through the Study PIs and Advisory Board.

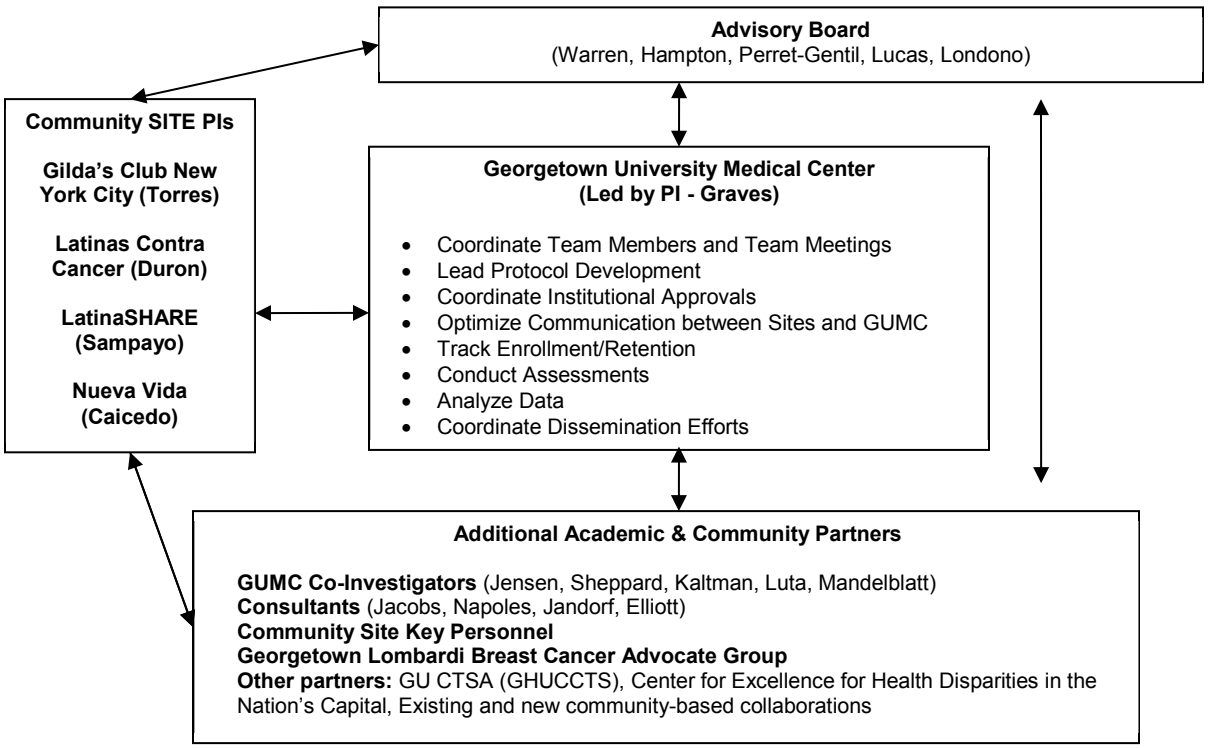
DISSEMINATION AND IMPLEMENTATION ASSESSMENT

Governance Plan

We will develop a governance plan for the project so that the roles and responsibilities of team members are clear. We define our team as involving researchers, community organizations, patient advocacy groups, consultants and our advisory board. We are fortunate that the diverse perspectives of the team members and their respective organizations complement and extend their individual capabilities beyond what any one group could do on its own. In this regard, we maximize the likelihood of successfully implementing the study, disseminating study results and incorporating them into practice. This synergy – and the perspectives and expertise behind it – will provide an excellent foundation for truly impacting and improving QOL among Latino families facing cancer.

At the first team meeting convened soon after study initiation, we will discuss the organizational structure and roles and responsibilities of the team members. Below we present a template for one possible structure that identifies the primary responsibilities of and interactions between the various groups involved in the study. Although Georgetown University is depicted as the "hub" as the prime institution and our experience with executing research studies, we are open to redefining these roles pending the input from the entire team.

Figure: Overview of Draft Organizational Structure



Resource Sharing / Fiscal and Management Coordination

Each PI will be responsible for managing their own budgets, although Dr. Graves will provide oversight and assist as needed with budget management. Each community partner has developed their own budget and

budget justification for the proposed study, including salary for the Site PI and key personnel, travel, supplies and other research expenses. The GUMC budget includes funds for annual honoraria ($1000) provided to Advisory Board members as well as annual Consultant stipends ($2000) and travel funds.

Procedure for Resolving Conflicts

If a potential conflict develops, the PIs at each site will first attempt to resolve the dispute on their own. They will then seek consultation from the members of the Advisory Board. However, if they are not able to resolve a particular dispute, the disagreement shall be referred to an arbitration committee consisting of one senior faculty member or administrator from each of the institutions in addition to an impartial senior executive mutually agreed upon by each of the PIs. Members of this arbitration committee will not be directly involved with the study. Decisions about publications and new collaborations will be made by the PIs with input from the Co-investigators and study team personnel.

Change in PI Location

If a PI moves to a new institution, attempts will be made to transfer the relevant portion of the grant and related work to the new institution. In the event that a PI cannot carry out her duties a new PI will be recruited as a replacement at one of the participating organizations subject to the approval of the organization and PCORI.

Methods for Disseminating and Implementing Evidence-Based Interventions into Community Settings

One of our team members, Dr. Anna Nápoles (Consultant) has recently submitted for review a manuscript that describes methods for translating evidence-based behavioral interventions into programs appropriate for community organizations that serve populations with heath disparities. One approach to address health disparities is to implement evidence-based interventions (EBI) that improve health and prevent disease and disabilities into community settings to reach disparity populations. Although many such EBIs are available, they are not being implemented broadly, especially in vulnerable communities. One reason is that there are few conceptual models of the translation processes that apply to the field of health disparities. Most models assume that one EBI is translated with minor adaptations, and communities are seldom involved in the process. However, successful translation into vulnerable communities usually requires numerous adaptations to EBIs to accommodate differences in populations, settings, and available resources. Also, communities often have locally developed programs (best practices) tailored to improve the health of their communities that can be integrated with EBIs to provide a better fit to the community. If our proposed research is successful in improving QOL outcomes for Latina breast cancer survivors and their caregivers, we will be guided by the a conceptual model described by Dr. Nápoles that integrates research-centered EBIs with community best practices. Along with feedback from our study partners and advisory board members, we will work to develop the PCI as a program to fit a new community context, meet the needs of a disparity population, capitalize on scientific evidence, and take into account the assets and limited resources characteristic of disparity communities. The model, derived primarily from two published translation frameworks, specifies seven phases that include establishing infrastructure for translation processes, identifying multiple inputs (EBIs and best practices), synthesizing the information, translating and adapting these to create an intervention, developing necessary capacity and delivering the intervention, and evaluating it using appropriate designs and measures. For each phase, we describe specific methodological steps and provide examples from the literature that focus on ethnic minority, low-income, and disabled disparity populations. The model and methods Dr. Nápoles proposes fill a gap in the literature and should help advance our ability to design and conduct studies to reach vulnerable communities with potentially effective interventions to reduce health disparities.

REFERENCES CITED

1. Ashing-Giwa KT, Padilla GV, Bohorquez DE, Tejero JS, Garcia M. Understanding the breast cancer experience of Latina women. *J Psychosoc Oncol,* 24(3):19-52; 2006. PM:17088240.
2. Graves KD, Jensen RE, Canar J, Perret-Gentil M, Leventhal KG, Gonzalez F, Caicedo L, Jandorf L, Kelly S, Mandelblatt J. Through the lens of culture: quality of life among Latina breast cancer survivors. *Breast Cancer Res Treat,* 136(2):603-613; 2012. PM:23085764.
3. Yanez B, Thompson EH, Stanton AL. Quality of life among Latina breast cancer patients: a systematic review of the literature. *J Cancer Surviv,* 5(2):191-207; 2011. PM:21274649. PMCID:PMC3096762
4. Eton DT, Cella D, Yost KJ, Yount SE, Peterman AH, Sledge GW. Minimally important differences on the functional assessment of cancer therapy-breast (FACT-B) scale: Results from ECOG study 1193. [Abstract 2142]. *Proc Am Soc Clin Oncol,* 22. http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=23&abstractID=100449 2003.
5. Gotay CC, Kawamoto CT, Bottomley A, Efficace F. The prognostic significance of patient-reported outcomes in cancer clinical trials. *J Clin Oncol,* 26(8):1355-1363; 2008. PM:18227528.
6. Badger TA, Segrin C, Hepworth JT, Pasvogel A, Weihs K, Lopez AM. Telephone-delivered health education and interpersonal counseling improve quality of life for Latinas with breast cancer and their supportive partners. *Psychooncology,*doi: 10.1002/pon.3101. [Epub ahead of print]; 2012. PM:22573418.
7. Jensen S, Given B. Fatigue affecting family caregivers of cancer patients. *Support Care Cancer,* 1(6):321-325; 1993. PM:8156250.
8. Kurtz ME, Kurtz JC, Given CW, Given B. A randomized, controlled trial of a patient/caregiver symptom control intervention: effects on depressive symptomatology of caregivers of cancer patients. *J Pain Symptom Manage,* 30(2):112-122; 2005. PM:16125026. PMCID:PMC1805478
9. Vitaliano PP, Zhang J, Scanlan JM. Is caregiving hazardous to one's physical health? A meta-analysis. *Psychol Bull,* 129(6):946-972; 2003. PM:14599289.
10. Marshall CA, Weihs KL, Larkey LK, Badger TA, Koerner SS, Curran MA, Pedroza R, Garcia FA. "Like a Mexican wedding": psychosocial intervention needs of predominately Hispanic low-income female co-survivors of cancer. *J Fam Nurs,* 17(3):380-402; 2011. PM:21813816.
11. Lopez-Class M, Gomez-Duarte J, Graves K, Ashing-Giwa K. A contextual approach to understanding breast cancer survivorship among Latinas. *Psychooncology,* 21(2):115-124; 2012. PM:21674680. PMCID:PMC3286615
12. Ashing-Giwa KT. The contextual model of HRQoL: a paradigm for expanding the HRQoL framework. *Qual Life Res,* 14(2):297-307; 2005. PM:15892421.
13. Bandura A. *Social Foundations of Thought and Action: A Social Cognitive Theory*. Englewood Cliffs, NJ, US: Prentice-Hall, Inc; 1986.
14. Graves KD. Social cognitive theory and cancer patients' quality of life: a meta-analysis of psychosocial intervention components. *Health Psychol,* 22(2):210-219; 2003. PM:12683741.
15. Lopez-Class M, Perret-Gentil M, Kreling B, Caicedo L, Mandelblatt J, Graves KD. Quality of life among immigrant Latina breast cancer survivors: realities of culture and enhancing cancer care. *J Cancer Educ,* 26(4):724-733; 2011. PM:21706194. PMCID:PMC3286609
16. Napoles-Springer AM, Ortiz C, O'Brien H, Diaz-Mendez M. Developing a culturally competent peer support intervention for Spanish-speaking Latinas with breast cancer. *J Immigr Minor Health,* 11(4):268-280; 2009. PM:18340533.
17. Nueva Vida. www.nueva-vida.org/index.php [accessed Oct. 1, 2012].
18. Sheppard VB, Figueiredo M, Canar J, Goodman M, Caicedo L, Kaufman A, Norling G, Mandelblatt J. Latina a Latina: developing a breast cancer decision support intervention. *Psychooncology,* 17(4):383-391; 2008. PM:17628037.

19. Sussner KM, Thompson HS, Valdimarsdottir HB, Redd WH, Jandorf L. Acculturation and familiarity with, attitudes towards and beliefs about genetic testing for cancer risk within Latinas in East Harlem, New York City. *J Genet Couns,* 18(1):60-71; 2009. PM:18686019. PMCID:PMC2750831
20. Schyve PM. Language differences as a barrier to quality and safety in health care: the Joint Commission perspective. *J Gen Intern Med,* 22 Suppl 2:360-361; 2007. PM:17957426. PMCID:PMC2078554
21. Bickell NA, Shastri K, Fei K, Oluwole S, Godfrey H, Hiotis K, Srinivasan A, Guth AA. A tracking and feedback registry to reduce racial disparities in breast cancer care. *J Natl Cancer Inst,* 100(23):1717-1723; 2008. PM:19033569. PMCID:PMC2727139
22. Gilda's Club New York City website. http://www.gildasclubnyc.org/index.php [accessed Dec. 13, 2012].
23. Self-Help for Women with Breast or Ovarian Cancer (SHARE) website. http://www.sharecancersupport.org/share-new/ [accsessed Dec. 13, 2012].
24. Latinas Contra Cancer website. http://www.latinascontracancer.org/ [accessed Dec. 13, 2012]. 2012.
25. U.S.Census Bureau, U.S.Department of Commerce, Economics and Statistics Administration. The Hispanic Population: 2010. 2010 Census Briefs. Report No. C2010BR-04 issued May 2011 by Sharon R. Ennis, Merarys Rios-Vargas, and Nora G. Albert. http://www.census.gov/prod/cen2010/briefs/c2010br-04.pdf [accessed Dec. 12, 2012].
26. American Cancer Society. Cancer Facts & Figures for Hispanics/Latinos 2012-2014. American Cancer Society: Atlanta, GA; 2012. http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-034778.pdf [accessed Dec. 13, 2012].
27. National Cancer Institute Cancer Survivor website. http://dccps.nci.nih.gov/ocs/definitions.html [accessed Dec. 17, 2012].
28. Ashing-Giwa KT, Tejero JS, Kim J, Padilla GV, Hellemann G. Examining predictive models of HRQOL in a population-based, multiethnic sample of women with breast carcinoma. *Qual Life Res,* 16(3):413-428; 2007. PM:17279444.
29. Janz NK, Mujahid MS, Hawley ST, Griggs JJ, Alderman A, Hamilton AS, Graff J, Katz SJ. Racial/ethnic differences in quality of life after diagnosis of breast cancer. *J Cancer Surviv,* 3(4):212-222; 2009. PM:19760151.
30. Epstein RM, Street RL Jr. Patient-Centered Communication in Cancer Care: Promoting Healing and Reducing Suffering. National Cancer Institute, NIH Publication No. 07-6225. Bethesda, MD, 2007. http://www.outcomes.cancer.gov/areas/pcc/communication/pcc_monograph.pdf [accessed Oct. 1, 2012].
31. Eversley R, Estrin D, Dibble S, Wardlaw L, Pedrosa M, Favila-Penney W. Post-treatment symptoms among ethnic minority breast cancer survivors. *Oncol Nurs Forum,* 32(2):250-256; 2005. PM:15759063.
32. Blinder VS, Patil S, Thind A, Diamant A, Hudis CA, Basch E, Maly RC. Return to work in low-income Latina and non-Latina white breast cancer survivors: a 3-year longitudinal study. *Cancer,* 118(6):1664-1674; 2012. PM:22009703. PMCID:PMC3263326
33. Wells JN, Cagle CS, Bradley P, Barnes DM. Voices of Mexican American caregivers for family members with cancer: on becoming stronger. *J Transcult Nurs,* 19(3):223-233; 2008. PM:18403715.
34. Given BA, Sherwood P, Given CW. Support for caregivers of cancer patients: transition after active treatment. *Cancer Epidemiol Biomarkers Prev,* 20(10):2015-2021; 2011. PM:21980009.
35. Kurtz ME, Kurtz JC, Given CW, Given BA. Depression and physical health among family caregivers of geriatric patients with cancer--a longitudinal view. *Med Sci Monit,* 10(8):CR447-CR456; 2004. PM:15277994.
36. Song JI, Shin DW, Choi JY, Kang J, Baik YJ, Mo H, Park MH, Choi SE, Kwak JH, Kim EJ. Quality of life and mental health in family caregivers of patients with terminal cancer. *Support Care Cancer,* 19(10):1519-1526; 2011. PM:21479527.
37. Yabroff KR, Kim Y. Time costs associated with informal caregiving for cancer survivors. *Cancer,* 115(18 Suppl):4362-4373; 2009. PM:19731345.

38. Morris ME, Grant M, Lynch JC. Patient-reported family distress among long-term cancer survivors. *Cancer Nurs,* 30(1):1-8; 2007. PM:17235213.
39. Dorros SM, Card NA, Segrin C, Badger TA. Interdependence in women with breast cancer and their partners: an interindividual model of distress. *J Consult Clin Psychol,* 78(1):121-125; 2010. PM:20099957. PMCID:PMC2843088
40. Marshall CA, Larkey LK, Curran MA, Weihs KL, Badger TA, Armin J, Garcia F. Considerations of culture and social class for families facing cancer: the need for a new model for health promotion and psychosocial intervention. *Fam Syst Health,* 29(2):81-94; 2011. PM:21688902.
41. Lu Q, Zheng D, Young L, Kagawa-Singer M, Loh A. A pilot study of expressive writing intervention among Chinese-speaking breast cancer survivors. *Health Psychol,* 31(5):548-551; 2012. PM:22229930.
42. Matthews AK, Tejeda S, Johnson TP, Berbaum ML, Manfredi C. Correlates of quality of life among African American and white cancer survivors. *Cancer Nurs,* 35(5):355-364; 2012. PM:22495496.
43. Ell K, Katon W, Xie B, Lee PJ, Kapetanovic S, Guterman J, Chou CP. One-year postcollaborative depression care trial outcomes among predominantly Hispanic diabetes safety net patients. *Gen Hosp Psychiatry,* 33(5):436-442; 2011. PM:21774987. PMCID:PMC3175272
44. Mendes de Leon CF, Czajkowski SM, Freedland KE, Bang H, Powell LH, Wu C, Burg MM, DiLillo V, Ironson G, Krumholz HM, Mitchell P, Blumenthal JA. The effect of a psychosocial intervention and quality of life after acute myocardial infarction: the Enhancing Recovery in Coronary Heart Disease (ENRICHD) clinical trial. *J Cardiopulm Rehabil,* 26(1):9-13; 2006. PM:16617220.
45. Ell K, Xie B, Kapetanovic S, Quinn DI, Lee PJ, Wells A, Chou CP. One-year follow-up of collaborative depression care for low-income, predominantly Hispanic patients with cancer. *Psychiatr Serv,* 62(2):162-170; 2011. PM:21285094.
46. Penedo FJ, Traeger L, Dahn J, Molton I, Gonzalez JS, Schneiderman N, Antoni MH. Cognitive behavioral stress management intervention improves quality of life in Spanish monolingual hispanic men treated for localized prostate cancer: results of a randomized controlled trial. *Int J Behav Med,* 14(3):164-172; 2007. PM:18062059.
47. Erwin DO, Johnson VA, Feliciano-Libid L, Zamora D, Jandorf L. Incorporating cultural constructs and demographic diversity in the research and development of a Latina breast and cervical cancer education program. *J Cancer Educ,* 20(1):39-44; 2005. PM:15876181.
48. Cancer Support Community. http://www.cancersupportcommunity.org/MainMenu/About-Cancer/Frankly-Speaking-About-Cancer/Internet-Radio-Show/Frankly-Speaking-About-Cancer-De-Cuidador-a-Cuidador.html. April 11, 2011 [accessed Oct. 1, 2012].
49. La Clinica Del Pueblo. http://www.lcdp.org/ [accessed Oct. 1, 2012].
50. National Council of La Raza (NCLR). Fortaleciendo la Familia Hispana: Approaches to Strengthening the Hispanic Family. Summary of Best Practices. http://www.nclr.org/images/uploads/pages/AMS/2010_FSA_Best_Practices.pdf [accessed Oct. 1, 2012]. 2010.
51. Bandura A. *Self-Efficacy: The Exercise of Control*. 1st ed. New York, NY: W.H. Freeman and Company; 1997.
52. Beck JS. *Cognitive Therapy: Basics and Beyond*. New York, NY: Guilford Publications; 1995.
53. Jacobs BJ. *The Emotional Survival Guide for Caregivers: Looking After Yourself and Your Family While Helping an Aging Parent*. New York, NY: The Guilford Press; 2006.
54. Sherwood PR, Given BA, Donovan H, Baum A, Given CW, Bender CM, Schulz R. Guiding research in family care: a new approach to oncology caregiving. *Psychooncology,* 17(10):986-996; 2008. PM:18203244.
55. DeWalt DA, Rothrock N, Yount S, Stone AA. Evaluation of item candidates: the PROMIS qualitative item review. *Med Care,* 45(5 Suppl 1):S12-S21; 2007. PM:17443114. PMCID:PMC2810630
56. Reeve BB, Hays RD, Bjorner JB, Cook KF, Crane PK, Teresi JA, Thissen D, Revicki DA, Weiss DJ, Hambleton RK, Liu H, Gershon R, Reise SP, Lai JS, Cella D. Psychometric evaluation and calibration

of health-related quality of life item banks: plans for the Patient-Reported Outcomes Measurement Information System (PROMIS). *Med Care,* 45(5 Suppl 1):S22-S31; 2007. PM:17443115.
57. Cella D, Yount S, Rothrock N, Gershon R, Cook K, Reeve B, Ader D, Fries JF, Bruce B, Rose M. The Patient-Reported Outcomes Measurement Information System (PROMIS): progress of an NIH Roadmap cooperative group during its first two years. *Med Care,* 45(5 Suppl 1):S3-S11; 2007. PM:17443116. PMCID:PMC2829758
58. Patient Reported Outcomes Measurement Information System (PROMIS), National Institutes of Health. http://www.nihpromis.org/measures/translations [accessed Oct. 1, 2012].
59. Institute of Medicine, National Research Council of the National Academies. *From Cancer Patient to Cancer Survivor: Lost in Transition*. Hewitt, M., Greenfield, S., and Stovall, E. eds. Washington, DC: The National Academies Press; 2006.
60. Hays RD, Farivar SS, Liu H. Approaches and recommendations for estimating minimally important differences for health-related quality of life measures. *COPD,* 2(1):63-67; 2005. PM:17136964.
61. Suh SY, Leblanc TW, Shelby RA, Samsa GP, Abernethy AP. Longitudinal patient-reported performance status assessment in the cancer clinic is feasible and prognostic. *J Oncol Pract,* 7(6):374-381; 2011. PM:22379420. PMCID:PMC3219464
62. Berg CA, Upchurch R. A developmental-contextual model of couples coping with chronic illness across the adult life span. *Psychol Bull,* 133(6):920-954; 2007. PM:17967089.
63. Manne S, Badr H, Kashy DA. A longitudinal analysis of intimacy processes and psychological distress among couples coping with head and neck or lung cancers. *J Behav Med,* 35(3):334-346; 2012. PM:21556790.
64. OncLive website article, "What oncologists should know about advocacy and support groups." http://www.onclive.com/publications/obtn/2011/may-2011/What-Oncologists-Should-Know-About-Advocacy-and-Support-Groups/1 [accessed Dec. 17, 2012].
65. Graves KD, Carter CL, Anderson ES, Winett RA. Quality of life pilot intervention for breast cancer patients: use of social cognitive theory. *Palliat Support Care,* 1(2):121-134; 2003. PM:16594274.
66. Sheppard VB, Williams KP, Harrison TM, Jennings Y, Lucas W, Stephen J, Robinson D, Mandelblatt JS, Taylor KL. Development of decision-support intervention for Black women with breast cancer. *Psychooncology,* 19(1):62-70; 2010. PM:19267384. PMCID:PMC3136087
67. Brady MJ, Cella DF, Mo F, Bonomi AE, Tulsky DS, Lloyd SR, Deasy S, Cobleigh M, Shiomoto G. Reliability and validity of the Functional Assessment of Cancer Therapy-Breast quality-of-life instrument. *J Clin Oncol,* 15(3):974-986; 1997. PM:9060536.
68. Buki LP, Garces DM, Hinestrosa MC, Kogan L, Carrillo IY, French B. Latina breast cancer survivors' lived experiences: diagnosis, treatment, and beyond. *Cultur Divers Ethnic Minor Psychol,* 14(2):163-167; 2008. PM:18426289.
69. Wallington SF, Luta G, Noone AM, Caicedo L, Lopez-Class M, Sheppard V, Spencer C, Mandelblatt J. Assessing the awareness of and willingness to participate in cancer clinical trials among immigrant Latinos. *J Community Health,* 37(2):335-343; 2012. PM:21805372.
70. SBM Community Award 2011, Nueva Vida, Inc. Awarded at the Annual Meeting of the Society of Behavioral Medicine, April 2011, Washington, DC.
71. Hurtado de Mendoza A, Gonzalez F, Serrano A, Kaltman S. Perceived causes of social isolation among Latina immigrants seeking primary care services. (Under review). 2012.
72. Kaltman S, Gonzalez F, Hurtado de Mendoza A., Serrano A, Mete M. Trauma exposure, mental health, and physical health among immigrants from Central and South America. (Under review). 2012.
73. Kaltman S, Hurtado de MA, Gonzales FA, Serrano A. Preferences for trauma-related mental health services among Latina immigrants from Central America, South America, and Mexico. *Psychol Trauma,* 2012.
74. Kaltman S, Hurtado de Mendoza A., Serrano A, Gonzalez F. A novel mental health intervention for low-income, trauma-exposed Latina immigrants in primary care. (Under review). 2012.

75. Jandorf L, Fatone A, Borker PV, Levin M, Esmond WA, Brenner B, Butts G, Redd WH. Creating alliances to improve cancer prevention and detection among urban medically underserved minority groups. The East Harlem Partnership for Cancer Awareness. *Cancer,* 107(8 Suppl):2043-2051; 2006. PM:16977600.
76. Jandorf L, Gutierrez Y, Lopez J, Christie J, Itzkowitz SH. Use of a patient navigator to increase colorectal cancer screening in an urban neighborhood health clinic. *J Urban Health,* 82(2):216-224; 2005. PM:15888638.
77. Thompson HS, Valdimarsdottir HB, Jandorf L, Redd W. Perceived disadvantages and concerns about abuses of genetic testing for cancer risk: differences across African American, Latina and Caucasian women. *Patient Educ Couns,* 51(3):217-227; 2003. PM:14630378.
78. Thompson HS, Valdimarsdottir HB, Winkel G, Jandorf L, Redd W. The Group-Based Medical Mistrust Scale: psychometric properties and association with breast cancer screening. *Prev Med,* 38(2):209-218; 2004. PM:14715214.
79. Erwin DO, Trevino M, Saad-Harfouche FG, Rodriguez EM, Gage E, Jandorf L. Contextualizing diversity and culture within cancer control interventions for Latinas: changing interventions, not cultures. *Soc Sci Med,* 71(4):693-701; 2010. PM:20646810.
80. Mandelblatt J, Kaufman E, Sheppard VB, Pomeroy J, Kavanaugh J, Canar J, Pallandre L, Cullen J, Huerta E. Breast cancer prevention in community clinics: will low-income Latina patients participate in clinical trials? *Prev Med,* 40(6):611-618; 2005. PM:15850856.
81. O'Malley AS, Gonzalez RM, Sheppard VB, Huerta E, Mandelblatt J. Primary care cancer control interventions including Latinos: a review. *Am J Prev Med,* 25(3):264-271; 2003. PM:14507536.
82. Sheppard VB, Cox LS, Kanamori MJ, Canar J, Rodriguez Y, Goodman M, Pomeroy J, Mandelblatt J, Huerta EE. Brief report: if you build it, they will come: methods for recruiting Latinos into cancer research. *J Gen Intern Med,* 20(5):444-447; 2005. PM:15963169. PMCID:PMC1490123
83. Graves KD, Huerta E, Cullen J, Kaufman E, Sheppard V, Luta G, Isaacs C, Schwartz MD, Mandelblatt J. Perceived risk of breast cancer among Latinas attending community clinics: risk comprehension and relationship with mammography adherence. *Cancer Causes Control,* 19(10):1373-1382; 2008. PM:18704716.
84. Warren AG, Londono GE, Wessel LA, Warren RD. Breaking down barriers to breast and cervical cancer screening: a university-based prevention program for Latinas. *J Health Care Poor Underserved,* 17(3):512-521; 2006. PM:16960319.
85. Assessment Center. http://www.assessmentcenter.net [accessed Oct. 1, 2012].
86. Gershon R, Rothrock NE, Hanrahan RT, Jansky LJ, Harniss M, Riley W. The development of a clinical outcomes survey research application: Assessment Center. *Qual Life Res,* 19(5):677-685; 2010. PM:20306332.
87. Hawley ST, Janz NK, Hamilton A, Griggs JJ, Alderman AK, Mujahid M, Katz SJ. Latina patient perspectives about informed treatment decision making for breast cancer. *Patient Educ Couns,* 73(2):363-370; 2008. PM:18786799.
88. Katz SJ, Lantz PM, Paredes Y, Janz NK, Fagerlin A, Liu L, Deapen D. Breast cancer treatment experiences of Latinas in Los Angeles County. *Am J Public Health,* 95(12):2225-2230; 2005. PM:16257945. PMCID:PMC1449511
89. Shelby RA, Scipio CD, Somers TJ, Soo MS, Weinfurt KP, Keefe FJ. Prospective study of factors predicting adherence to surveillance mammography in women treated for breast cancer. *J Clin Oncol,* 30(8):813-819; 2012. PM:22331949. PMCID:PMC3295570
90. Kaltman S, Hurtado de Mendoza A., Gonzales FA, Serrano A, Guarnaccia PJ. Contextualizing the trauma experience of women immigrants from Central America, South America, and Mexico. *J Trauma Stress,* 24(6):635-642; 2011. PM:22144133.
91. Napoles AM, Chadiha L, Eversley R, Moreno-John G. Reviews: developing culturally sensitive dementia caregiver interventions: are we there yet? *Am J Alzheimers Dis Other Demen,* 25(5):389-406; 2010. PM:20508244.

92. Miller WR, Rollnick S. *Motivational Interviewing: Preparing People for Change*. 2nd ed. New York, NY: Guilford Publications; 2002.
93. Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, Ogedegbe G, Orwig D, Ernst D, Czajkowski S. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol,* 23(5):443-451; 2004. PM:15367063.
94. Baxter NN, Goodwin PJ, McLeod RS, Dion R, Devins G, Bombardier C. Reliability and validity of the body image after breast cancer questionnaire. *Breast J,* 12(3):221-232; 2006. PM:16684320.
95. Pargament KI, Koenig HG, Perez LM. The many methods of religious coping: development and initial validation of the RCOPE. *J Clin Psychol,* 56(4):519-543; 2000. PM:10775045.
96. Lugo Steidel AG, Contreras JM. A new familism scale for use with Latino populations. *Hispanic J Behav Sci,* 25(3):312-330; 2003.
97. Marin G, Sabogal F, Marin BV, Otero-Sabogal R, Perez-Stable EJ. Development of a short acculturation scale for Hispanics. *Hispanic J Behav Sci,* 9(2):183-205; 1987.
98. Merluzzi TV, Nairn RC, Hegde K, Martinez Sanchez MA, Dunn L. Self-efficacy for coping with cancer: revision of the Cancer Behavior Inventory (version 2.0). *Psychooncology,* 10(3):206-217; 2001. PM:11351373. PMCID:PMC2945365
99. Merluzzi TV, Philip EJ, Vachon DO, Heitzmann CA. Assessment of self-efficacy for caregiving: the critical role of self-care in caregiver stress and burden. *Palliat Support Care,* 9(1):15-24; 2011. PM:21352614.
100. Broadhead WE, Gehlbach SH, de Gruy FV, Kaplan BH. The Duke-UNC Functional Social Support Questionnaire. Measurement of social support in family medicine patients. *Med Care,* 26(7):709-723; 1988. PM:3393031.
101. Derogatis LR, Melisaratos N. The Brief Symptom Inventory: an introductory report. *Psychol Med,* 13(3):595-605; 1983. PM:6622612.
102. Fries JF, Bruce B, Rose M. Comparison of the health assessment questionnaire disability index and the short form 36 physical functioning subscale using Rasch analysis: comment on the article by Taylor and McPherson. *Arthritis Rheum,* 59(4):598-599; 2008. PM:18383400.
103. Fries JF, Cella D, Rose M, Krishnan E, Bruce B. Progress in assessing physical function in arthritis: PROMIS short forms and computerized adaptive testing. *J Rheumatol,* 36(9):2061-2066; 2009. PM:19738214.
104. Revicki DA, Chen WH, Harnam N, Cook KF, Amtmann D, Callahan LF, Jensen MP, Keefe FJ. Development and psychometric analysis of the PROMIS pain behavior item bank. *Pain,* 146(1-2):158-169; 2009. PM:19683873. PMCID:PMC2775487
105. Rose M, Bjorner JB, Becker J, Fries JF, Ware JE. Evaluation of a preliminary physical function item bank supported the expected advantages of the Patient-Reported Outcomes Measurement Information System (PROMIS). *J Clin Epidemiol,* 61(1):17-33; 2008. PM:18083459.
106. Cella D, Riley W, Stone A, Rothrock N, Reeve B, Yount S, Amtmann D, Bode R, Buysse D, Choi S, Cook K, Devellis R, DeWalt D, Fries JF, Gershon R, Hahn EA, Lai JS, Pilkonis P, Revicki D, Rose M, Weinfurt K, Hays R. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *J Clin Epidemiol,* 63(11):1179-1194; 2010. PM:20685078. PMCID:PMC2965562
107. Samsa G, Edelman D, Rothman ML, Williams GR, Lipscomb J, Matchar D. Determining clinically important differences in health status measures: a general approach with illustration to the Health Utilities Index Mark II. *Pharmacoeconomics,* 15(2):141-155; 1999. PM:10351188.
108. Makoul G, Krupat E, Chang CH. Measuring patient views of physician communication skills: development and testing of the Communication Assessment Tool. *Patient Educ Couns,* 67(3):333-342; 2007. PM:17574367.

109. Napoles AM, Gregorich SE, Santoyo-Olsson J, O'Brien H, Stewart AL. Interpersonal processes of care and patient satisfaction: do associations differ by race, ethnicity, and language? *Health Serv Res,* 44(4):1326-1344; 2009. PM:19490162. PMCID:PMC2714869
110. Khatcheressian JL, Hurley P, Bantug E, Esserman LJ, Grunfeld E, Halberg F, Hantel A, Henry NL, Muss HB, Smith TJ, Vogel VG, Wolff AC, Somerfield MR, Davidson NE. Breast cancer follow-up and management after primary treatment: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol,* Dec 10. [Epub ahead of print].: doi: 10.1200/JCO.2012.45.9859; 2012. PM:23129741.
111. Sabatino SA, Thompson TD, Richardson LC, Miller J. Health insurance and other factors associated with mammography surveillance among breast cancer survivors: results from a national survey. *Med Care,* 50(3):270-276; 2012. PM:22193416.
112. Northouse LL. Social support in patients' and husbands' adjustment to breast cancer. *Nurs Res,* 37(2):91-95; 1988. PM:3347526.
113. Northouse LL, Mood DW, Schafenacker A, Kalemkerian G, Zalupski M, Lorusso P, Hayes DF, Hussain M, Ruckdeschel J, Fendrick AM, Trask PC, Ronis DL, Kershaw T. Randomized clinical trial of a brief and extensive dyadic intervention for advanced cancer patients and their family caregivers. *Psychooncology,* doi: 10.1002/pon.3036. [Epub ahead of print] 2012. PM:22290823. PMCID:PMC3387514
114. Rakowski W, Ehrich B, Dube CE, Pearlman DN, Goldstein MG, Peterson KK, Rimer BK, Woolverton H. Screening mammography and constructs from the transtheoretical model: associations using two definitions of the stages-of-adoption. *Ann Behav Med,* 18(2):91-100; 1996.
115. Lepore SJ, Silver RC, Wortman CB, Waymetn HA. Social constraints, intrusive thoughts, and depressive symptoms among bereaved mothers. *Journal of Personality and Social Psychology,* 70(2):271-282; 1996.
116. Schnur JB, Valdimarsdottir HB, Montgomery GH, Nevid JS, Bovbjerg DH. Social constraints and distress among women at familial risk for breast cancer. *Ann Behav Med,* 28(2):142-148; 2004. PM:15454362.
117. Dane AV, Schneider BH. Program integrity in primary and early secondary prevention: are implementation effects out of control? *Clin Psychol Rev,* 18(1):23-45; 1998. PM:9455622.
118. Peshkin BN, Demarco TA, Graves KD, Brown K, Nusbaum RH, Moglia D, Forman A, Valdimarsdottir H, Schwartz MD. Telephone genetic counseling for high-risk women undergoing BRCA1 and BRCA2 testing: rationale and development of a randomized controlled trial. *Genet Test,* 12(1):37-52; 2008. PM:18373403.
119. Mackinnon DP, Lockwood CM, Williams J. Confidence limits for the indirect effect: distribution of the product and resampling methods. *Multivariate Behav Res,* 39(1):99; 2004. PM:20157642. PMCID:PMC2821115
120. Siminoff LA, Ravdin P, Colabianchi N, Sturm CM. Doctor-patient communication patterns in breast cancer adjuvant therapy discussions. *Health Expect,* 3(1):26-36; 2000. PM:11281909.

PROTECTION OF HUMAN SUBJECTS

PROTECTION OF HUMAN SUBJECTS

We will obtain approval by the Joint Oncology Georgetown University Medical Center / Georgetown University Hospital, the St. Luke's Breast Service Hospital Institutional Review Board (New York City) and any other relevant Institutional Review Boards in New York, NY or San Jose, CA. We will fully disclose the potential risks and benefits to all study participants and give them ample opportunity to refuse participation or skip questions they do not want to answer. Oral and written consent will be acquired for all participants. Participants will be informed that their healthcare and related services will not be impacted if they decline to participate in the study. Documentation is provided here for each point relevant to the conduct of research with Human Subjects.

1. RISKS TO THE SUBJECTS

a. Human Subjects Involvement, Characteristics, and Design

For the proposed study, we will recruit participants from local hospitals and community-based organizations including: LatinaSHARE (New York, NY), Nueva Vida Inc. (Washington, DC), Latinas Contra Cancer (New York, NY) Gilda's Club NYC (New York, NY) and St. Luke's-Roosevelt Hospital (New York, NY). We may also receive referrals to the study through existing collaborations of study team members with St. Barnabas Hospital (New York, NY), Doctors Community Hospital (Lanham, MD) and Signature Breast Care (Lanham, MD). The proposed study consists of **refining the intervention** and a **randomized controlled trial**. The study population will be Latina breast cancer survivors and their caregivers. Caregivers will be a primary support person identified by the survivor. We anticipate that 10 patient-caregiver dyads will participate in refining the intervention, and 125 patient-caregiver dyads will participate in the randomized trial (allowing for attrition, we expect a final sample size of 100 dyads). Latina breast cancer survivors will be eligible for this study if they: 1) 1) self-identify as Latina, 2) have been diagnosed with breast cancer, 3) speak English or Spanish, 4) can provide meaningful consent (i.e. men and women with severe cognitive impairment will be excluded), 5) can identify at least one primary, adult caregiver. Caregivers of Latina breast cancer survivors will be eligible if they: 1) are aged 21 to 80 years, 2) speak English or Spanish, 3) can provide meaningful consent (i.e. men and women with severe cognitive impairment will be excluded). Following IRB approval and with a HIPAA waiver, contacts at each community site (LatinaSHARE, Nueva Vida, Latinas Contra Cancer, Gilda's Club NYC) will help identify eligible Latina survivors and will mail a bilingual study invitation letter inviting them and a primary caregiver to be involved in refining the intervention or the randomized controlled trial. Potential participants will be provided with several easy ways to decline the study or opt out of additional contact. For example, study invitation letters will include a pre-stamped decliner postcard and a telephone number to call a study-dedicated line. Those who do not decline within 2 weeks of receipt of the study letter will be contacted via telephone by a member of the study team. During this initial telephone screening call, women will be invited to decline if they are not interested. If they are interested, the research assistant will further explain the study and determine initial eligibility based on self-reported cancer history, age and ethnicity. We will also use in-person recruitment to talk with survivors and caregivers at the four sites. If a survivor and/or caregiver is interested, a study team member will follow up with further information about the study to determine eligibility and obtain consent from both individuals in the dyad. Our community partners at Nueva Vida have had success recruiting caregivers into their program by encouraging the Latina survivors to invite the caregivers into the program. We will use this strategy and others developed by the study team to recruit both survivors and caregivers into the proposed project.

Refining the Intervention. We will recruit 10 patient-caregiver dyads to complete individual and joint qualitative interviews to provide feedback on the intervention. The interviews will take approximately 45

minutes to complete, for which participants will be remunerated $20 each ($40 per survivor-caregiver dyad). The intervention protocol will be further revised following the feedback from these interviews and input from the research team, consultants and advisory board.

Randomized Controlled Trial. For the randomized controlled trial, we anticipate enrolling 125 patient-caregiver dyads, of which we expect 100 to remain enrolled and complete the study protocol through the 6-month follow-up assessment interview. Involvement in the randomized controlled trial will consist of participation in a baseline telephone interview at initiation, two follow-up telephone interviews (one after completion of the intervention and another 6-months post intervention) and, for survivor-caregiver dyads randomized to the patient-caregiver intervention (PCI), attendance at eight 2-hour intervention sessions held twice a month at one of the four recruitment sites. Survivor-caregiver dyads randomized to usual care (UC) will be invited to take part in any and all services normally available to them through the four community organizations, including support groups, patient navigation, social events and educational workshops.

b. Sources of Materials.

The primary source for research materials will be confidential telephone-based interviews with survivors and caregivers. In addition, all interventionists will complete quality assessment forms after each intervention session. These forms will not contain protected health information, only general comments about topics covered, the number of attendees and length of session. Measures include: sociodemographics, medical history, breast cancer stigma/shame, religious coping, familismo, acculturation, communication with providers, communication with caregivers, medical mistrust, communication self-efficacy, social support, distress, dyadic social support, dyadic perspective and social constraints, satisfaction with care and adherence to breast cancer follow-up care. Data we obtain from community sites will include contact and basic demographic information about the potential participants: name, address and telephone number. This basic demographic information will not be included on the document containing final interview data.

c. Potential Risks.

Risks associated with participating in this study are minimal and fall into two categories:

1.) First is the risk associated with completing the study interviews. There is a low risk of adverse psychological reactions to the study interviews. As noted above, we will ask participants for information related to sociodemographics, medical history, breast cancer stigma/shame, religious coping, familismo, acculturation, communication with providers, communication with caregivers, medical mistrust, communication self-efficacy, social support, distress, dyadic social support, dyadic perspective and social constraints, satisfaction with care and adherence to breast cancer follow-up care. In our experience, these questions do not cause any discomfort to participants, and they will be instructed that they can choose to skip any question they do not wish to answer. It is possible that these questions may generate increased worry for some individuals. Of note, members of the research team have been conducting research with human subjects related to cancer for over a decade and thus have experience managing participant discomfort in the rare situations it arises (e.g. Dr. Graves, 13 years, Dr. Sheppard, 10 years). Our team also includes licensed mental health professionals who will be able to provide referrals as needed to any distressed participants (e.g., Drs. Jacobs, Kaltman; Ms. Torres).

We also consider participation in the in-depth interviews to refine the intervention to be of minimal risk, as participants will be responding to questions about their opinions regarding the intervention materials, topics, format and procedures. For this, participants may not want to have their responses to qualitative interviews audiorecorded; for individuals who do not agree to audiotaping, a trained research team member will take written notes.

2.) Second, there may be risks associated with participation in the PCI intervention related to discussion of cancer diagnosis, treatment experience and coping skills. Of note, these risks are no different than those of participants receiving usual care. All interventionists are bilingual and bi-cultural and will receive extensive training. If any member of the study team notes that a participant is reporting high levels of distress or difficulty coping with her diagnosis or treatment, we will use our established protocol for assessing and managing distress. Specifically, we will ask the participant's permission to have a mental health professional member of our team (e.g., Drs. Kristi Graves, Stacey Kaltman or Ms. Torres) follow up with a telephone call to the participant. These team members have experience in assessing distress among participants in cancer research and/or Latina survivors and their caregivers. If appropriate, the participant will be provided with resources for additional psychological support. We have a list of consultation psychiatry services, social work services, and mental health practitioners in private practice that provide clinical services to patients and families. We will ensure each study site has this list updated and available to study team members prior to participant enrollment.

2. ADEQUARY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent

We will take several steps to protect the autonomy of subjects and to assure that the consent is truly informed. Recruitment of participants will occur through notification of the study with an invitation letter or through in person recruitment at one of the community sites. For those who do not decline further contact, they will receive a follow-up telephone invitation to participate. We will then mail all participants packets with informed consent documents and postage paid return envelopes. If a participant is unable to read, a member of the study team will read the consent document in its entirety to them over the phone. If written informed consent on an IRB-approved consent document has not yet been obtained prior to completion of the baseline interview for both intervention refinement and the randomized controlled trial, a member of the study team will obtain each participant's verbal consent to conduct the interview. We have followed similar IRB-approved procedures in past studies. Importantly, participants will not receive their intervention assignment until we have all signed written consents on file. Consent will consist of a signature on a form describing the nature of the study. The major sections of the consent form include: (a) the research purpose and description of the study, (b) the potential benefits/risks of the study, (c) confidentiality of the data, (d) the voluntary nature of the study, (e) the freedom to refuse to answer any specific questions or to withdraw from the study at any time, (f) a statement that there are no costs of the study to the participant, (g) a list of persons to contact with questions or concerns, and (h) amount that they will be compensated per interview and per intervention session ($20 for qualitative interview in refining the intervention, $10 per telephone interview for randomized controlled trial and $10 per intervention session). Of note, participants assigned to UC will receive the same overall amount of study incentives over the course of the study timeline. Participants will be given a copy of the consent form, and one copy will be retained for study records. The PI will ensure that these forms are stored in locked filing cabinets. We anticipate that all signed consent documents will be returned to and retained at the GUMC study site. We will discuss these procedures and make adjustments as needed pending review by the study team at the initial study meeting.

b. Protection Against Risk

All members of the research team and personnel involved in recruitment will complete the necessary Human Subjects and HIPAA Training (e.g., CITI Courses), and copies of these certifications will be kept on file with the PI. The GUMC Project Director will be responsible for guiding the study staff at each of our community partners on the training procedures (e.g., ensuring they have the right website, tracking when the training is complete). If at any point a participant states that they are experiencing any psychological discomfort, they will be given an opportunity to discontinue the study and/or provided with a list of local support services per our

established distress protocol. At GU, several resources exist for training in the responsible conduct of research. We are fortunate to have access to the full resources of the Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS). For example, GHUCCTS has a strong program in Regulatory and Ethics Knowledge and Support. The mission of this program is to promote and preserve research integrity through training and support related to the application of ethical principles to the design and implementation of translational research. These programs are an active part of the Training in the Responsible Conduct of Research and Human Subjects Protection available to all of the researchers at LCCC. When possible, we will make these training resources available to all study team members. For example, we may be able to include a presentation by a member of the GHUCCTS program in Regulatory and Ethics Knowledge and Support during our initial team meeting.

Our plan for maintaining confidentiality is multifaceted. At Georgetown, data security measures include 256-bit SSL encryption, industry-standard firewall, IP address filtering, corporate anti-virus software, domain-authenticated user controls, and daily data backups. Of note, each of the study sites has included funds to purchase a new computer for research purposes. Our database administrator will work with the sites to ensure that the computer they purchase will include the appropriate security software and infrastructure. The protection of privacy of participants in studies is of the utmost importance. First, we will minimize communications across study sites that involve names or other identifying information. Where this is unavoidable (e.g., sites transmitting names to LCCC for recruitment of patients), all communications will be made via priority overnight mail, on a study-dedicated fax machine or via encrypted connections such as GUShare or a study-specific and encrypted cloud-based database (as opposed to e-mail). Second, all research files will be kept in locked files in research team offices and identified only by a randomly generated study ID number. Third, at the individual sites, all clinical information will be kept in locked files and/or secured dedicated services. Fourth, as we have done in our prior and current work, we will obtain a federal Certificate of Confidentiality to protect confidentiality of study participants. Finally, in all data sets, we will use ID numbers only. A separate data set linking names with ID numbers will be accessible only through password protected and secure data programs and available only to trained study staff.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

We hope that participation in the proposed study will provide direct benefits to participants, including improved quality of life. We hope we will enable participants to learn new coping skills and strengthen their relationship with their caregiver. Moreover, all participants will be making a contribution to our understanding of quality of life and survivorship care among Latino families facing cancer. If hypotheses are supported, the intervention tested in the present study could be implemented at many community organizations and hospitals across the United States (e.g., the over 150 affiliate and satellite locations of the Cancer Support Community through our team members' affiliations with this organization). In addition, these findings could be applied to a number of other health conductions, thus making contributions to public health in other ways. Participants we are recruiting are participating on a voluntary basis and can withdraw at any time. Participants randomized to receive usual care will be given the opportunity to receive the intervention after completion of the 6-month follow up assessment.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

The goal of this project is to evaluate an empirically-supported psychosocial intervention with a diverse Latina survivor and caregiver community. Latina breast cancer survivors report lower quality of life than non-Latina survivors and the friends and family of Latina cancer patients are also significantly impacted. Few psychosocial interventions have been tested among Latina breast cancer survivors and their caregivers. Our proposed study will help close that gap. Conduct of rigorous and theoretically-grounded research like the proposed study is essential to the improvement of clinical care.

5. DATA AND SAFETY MONITORING PLAN

1) *Monitoring the progress of trials and the safety of participants*: We will create a Data Safety Monitoring Board (DSMB) for this project. We have identified a group of faculty and community partners not associated with the study team to monitor study progress as needed. This team includes:

   a. LCCC faculty: Sherrie Wallington, Ph.D. (Community Research; Health Disparities)
   b. Georgetown University Hospital: Ruth He, M.D. (Medical Oncology), Georgeen Newland, RN (Oncology nurse)
   c. Local experts from Community Organizations:
      i. Jose Mendoza, M.D. (Patient Advocate for Latinos, Colon Cancer Alliance)
      ii. Florencia Gonzales (Community-Based Research with Latinos)

This team will review our project enrollment, risk procedures, adverse event procedures, and quality assurance procedures twice each year by reviewing any adverse events reported and adherence to our eligibility monitoring rules. Further, the project director and the PI will be responsible for monitoring and reported participants' responses during the telephone interviews and intervention sessions. In particular, participants' responses to the interventions will be closely assessed at all time points through weekly GUMC meetings held with the PI, project director and other relevant study personnel. Likewise, we will review key events as appropriate during monthly teleconferences and/or at annual team meetings.

2) *Plans for assuring compliance with requirements regarding adverse event reporting*: Adverse events will be reported by the PI to Georgetown University IRB and to the appropriate PCORI offices.

CONSORTIUM/CONTRACTUAL ARRANGEMENTS

Georgetown University Medical Center (GUMC) has developed arrangements for subcontracts with each of the four community organizations: Gilda's Club New York City, NY; Latinas Contra Cancer, San Jose, CA; Nueva Vida Inc., Washington, DC; and SHARE, LatinaShare, New York, NY.

Each of these four partners will participate in all aspects of the proposed study, from refining the intervention at study initiation to disseminating results and identifying practical strategies for incorporating the patient-caregiver intervention into clinical practice at organizations, clinics and hospitals across the country. Each partner brings numerous strengths to the proposed work, as highlighted below and elsewhere throughout the application. Of note, each of our partners has won awards for their work with Latina breast cancer survivors and their families and provides support and care in linguistically- and culturally-sensitive ways. Personnel at each site are bilingual in English and Spanish. Further, each partner serves its clients/members in slightly different ways, allowing for the evaluation of our patient-caregiver intervention to be conducted in real-world settings, with diverse patients and caregivers and carried out by different types of interventionists.

Gilda's Club New York City, NY (GCNYC): GCNYC opened their doors in June 1995 to create a welcoming and supportive community for anyone affected by cancer. GCNYC's free program has offered support and networking groups, educational lectures, workshops and social events to over 7,300 members. The proposed project fits well with GCNYC's current support services. For example, two of the GCNYC's programs, Team Convene and Family Focus, provide forums in which our members and their family and friends can create plans for managing the illness or openly discuss concerns and fears that occur when living with cancer. Among other strengths, specific strengths that GCNYC brings to the overall project include:

- GCNYC has a large number of members (7,300) including many Latinos facing cancer. Their Manhattan-based Clubhouse has had over 100,000 member visits.
- GCNYC has existing programs for family and caregivers included in the support services.
- GCNYC is part of a world-wide network of Clubhouses, including affiliation with the Cancer Support Community (CSC), which has more than 50 local CSC affiliates and 100 satellite locations and online serves. These Clubhouses and CSC affiliates provide support and care services to hundreds of thousands of people living with cancer.
- GCNYC offers the strong support of CEO Lily Safani for the proposed project, including guidance to the study team on outreach and dissemination of results to other Gilda's Clubhouses and the CSC's network of affiliates.

Latinas Contra Cancer, San Jose, CA (LCC): LCC was founded in 2003 by Ysabel Duron, a journalist and cancer survivor. Her diagnosis propelled her to create LCC as a non-profit organization that primarily serves low-income, immigrant and Spanish speaking Latinos. LCC aims to diminish the fear surrounding the word cancer in the Latino community and increase understanding about prevention, screening and treatment. LCC also seeks to engage with researchers to examine the cultural, linguistic and economic barriers to access and early detection. LCC provides patient navigation services in Santa Clara County and has conducted hundreds of educational workshops, including culturally-focused social events which include information about cancer screening. Among many strengths, LCC brings the following assets to the overall project:

- LCC has a large percentage of clients who are immigrants from Mexico or of Mexican-American origin and thus expands the representativeness of the geographic and ethnic diversity of the proposed sample.
- LCC has trained over 100 patient navigators / promotoras in the region to provide culturally-sensitive and linguistically-appropriate care and education to cancer patients and the community.

- LCC is under the strong leadership of Ysabel Duron, a visible and connected advocate for issues related to Latino health and cancer.
- LCC organizes the biennial Latina Cancer Summit, a national conference established in 2008 that brings together leaders, advocates, promotoras, patient navigators, researchers, public health workers and policy makers to address issues relevant to Latinos and cancer. In 2014 and 2016, The Summit will be an important avenue for dissemination of study results and potential training for other organizations to incorporate the patient-caregiver intervention into the services they provide to Latinos facing cancer.

Nueva Vida, Inc., Washington DC: Nueva Vida, Inc. was founded in 1996 by a group of Latina breast cancer survivors and health care professionals in the Mid-Atlantic region. Led by executive director Larisa Caicedo, Nueva Vida provides a broad continuum of culturally sensitive cancer support services for Latinas in the Washington DC, Baltimore and Richmond metropolitan areas. As the only independent survivor-driven cancer care organization for Latinas in the area, Nueva Vida serves over 4,000 individuals and their families, and reaches countless more as a resource to local and national healthcare partners seeking to improve care for Latinas. These services include patient navigation and assistance from diagnosis and treatment to recovery, survival and end of life care, community outreach and education, support groups for patients and their families, and collaboration with local and national cancer researchers. Below we enumerate a few of the many strengths that Nueva Vida brings to the overall project:

- Nueva Vida co-founder Gloria Elliott (Consultant) developed the patient-caregiver intervention to be tested in the proposed work.
- Nueva Vida currently implements the intervention with Latina survivors and caregivers.
- Nueva Vida and GUMC have partnered for more than a decade.
- Nueva Vida has won national awards that recognize its implementation of empirically-based programs to improve health in underserved communities.
- Nueva Vida has offices in Baltimore, MD and Richmond, VA and thus has a broad catchment area in the Mid-Atlantic region.

Self-Help for Women with Breast or Ovarian Cancer (SHARE), LatinaSHARE, New York City, New York: SHARE is group of and for breast and ovarian cancer survivors and their caregivers, founded in 1976. SHARE's mission is to create and sustain a supportive network and community of women affected by breast or ovarian cancer. SHARE brings these women and their families and friends together with others who have experienced breast or ovarian cancer, and provides participants with the opportunity to receive and exchange information, support, strength and hope. LatinaSHARE was started in the late 1980's to provide support, information, education and advocacy opportunities for the Latino community. LatinaSHARE's work focuses on empowerment, education and advocacy to bring about better health care, an improved quality of life, and a cure for these diseases. LatinaSHARE, co-directed by Jennie Santiago (Project Manager on the proposed study), offers telephone support, support groups, patient navigation and educational programs in Spanish for women in the greater New York area. LatinaSHARE brings a number of strengths to the overall project, including:

- LatinaSHARE provides support and services to women with breast or ovarian cancer through a trained peer-support model.
- LatinaSHARE's partnership in the proposed project is led by Ivis Sampayo, a recognized leader in patient advocacy and participant on numerous national panels and committees related to reducing disparities and improving Latina cancer outcomes.
- LatinaSHARE has developed online and print novellas to help educate Latina women about breast cancer. These experiences and products may serve as models for dissemination of study results and avenues to train other organizations on how to incorporate the intervention into practice.

Inter-Organizational Agreement Information

Key personnel for the proposed work include the Site Principal Investigator at each of the subcontract organizations, a Project Manager/Director and then any other key personnel deemed necessary for completion of the work at each specific site. Budget and budget justification details are provided for each of the subcontracting organizations in the Budget section of the uploaded application.

Each partner organization has submitted the following documents to GUMC:

1) Letter of Intent – This document indicates the intent of both GUMC and the subcontractor to establish the structural and financial arrangements needed to carry out the proposed work. In addition, this document indicates the subcontractor's agreement to follow GUMC's policies related to disclosure of any potential conflicts of interest specific to this study. Each Letter of Intent has been signed by the authorized officials at each of GUMC and each of the collaborator community organizations.

2) Statement of Work – This document indicates the scope of work to be carried out by each of the collaborator community organizations. These details include: participating in annual team meetings, conference calls and interventionist training; implementing the patient-caregiver intervention; and reporting and tracking of potential and enrolled participants and the expected number of enrolled participants recruited at each site during each of the study years. The estimates for the number of participants to be enrolled at each site were established through discussion with each of the subcontractors to reflect the realistic capacity to carry out the proposed research within the specific time and fiscal constraints. All four organizations will implement the patient-caregiver intervention and will participate fully in all aspects of the study, including use of a GUMC-central randomization system to randomize participants to either the intervention or usual care. This document was signed and dated by each of the subcontract PIs and Dr. Graves from GUMC.

3) Budget and Budget Justification – As required by both the PCORI submission guidelines and GUMC processes for subcontractors, each subcontract site submitted a detailed budget for each of the years of the proposed study along with an accompanying budget justification. Each site prepared and submitted to GUMC for review their budget and budget justification. As evident from the budget documents submitted from the four organizations, each one identified the administrative and personnel structure and organization that would work best for their individual site.

PROJECT PLAN AND TIMELINE

Below is our study timeline, with study tasks, milestones and deliverables and their estimated dates of submission or completion. Deliverables are highlighted in the left-hand column with shading.

Study Timeline	**YEAR 1: 5/13 – 4/14**				**YEAR 2: 5/14 – 4/15**				**YEAR 3: 5/15 – 4/16**			
Task / Deliverable	Q1 5/13 - 7/13	Q2 8/13 - 10/13	Q3 11/13- 1/14	Q4 2/14 - 4/14	Q1 5/14 - 7/14	Q2 8/14 - 10/14	Q3 11/14- 1/15	Q4 2/15 - 4/15	Q1 5/15 - 7/15	Q2 8/15 - 10/15	Q3 11/15- 1/16	Q4 2/16 - 4/16
Notify Team / Confirm Initial Team Meeting Dates	X											
Hire and Train GUMC Research Staff	X											
Conduct and Monitor Staff Training: NY, CA	X	X	X									
Convene Initial Team Meeting[a]	X											
Hold Monthly Team Teleconferences	X	X	X	X	X	X	X	X	X	X	X	X
Refine Protocols for Interviews; Recruitment; Intervention; Interventionist Training	X	X										
Submit IRBs		X										
Conduct In-Depth Interviews		X	X									
Develop Study Database and Randomization Procedures		X	X									
Refine Intervention Protocol / Surveys		X	X									
Conduct Interventionist Training: New York[b]			X									
Conduct Interventionist Training: CA[c]			X									
Beta Test PROMIS CAT System[d]												
Write and Submit Intervention Protocol Development Paper			X	X								
Amend IRBs as needed			X	X								
Register RCT at www.Clincialtrials.gov			X									
RCT Recruitment			X	X	X	X	X	X	X	X	X	
Initiate and Conduct RCT				X	X	X	X	X	X	X	X	
Complete Baseline, Post-Test and Follow-up Assessments (GUMC)			X	X	X	X	X	X	X	X	X	
Submit Study Protocol / Year 1 Report to PCORI				X								

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Graves, Kristi, Dove

Study Timeline	**YEAR 1: 5/13 – 4/14**				**YEAR 2: 5/14 – 4/15**				**YEAR 3: 5/15 – 4/16**			
Task / Deliverable	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
	5/13 - 7/13	8/13 - 10/13	11/13- 1/14	2/14 - 4/14	5/14 - 7/14	8/14 - 10/14	11/14- 1/15	2/15 - 4/15	5/15 - 7/15	8/15 - 10/15	11/15- 1/16	2/16 - 4/16
Convene Annual Team Meetings[a]	X					X					X	
Continue Recruitment / Troubleshoot if Low Enrollment				X	X	X	X	X	X	X		
Continue RCT / Address Implementation Issues as needed				X	X	X	X	X	X	X		
Collect Quality Assurance Data for Intervention Fidelity Checks				X		X		X		X		X
Convene Community Meeting: CA				X				X			X	
Prepare and Submit Abstract for the National Latino Cancer Summit			X	X								
Attend the National Latino Cancer Summit					X							
Submit Year 2 Report to PCORI								X				
Discuss Dissemination Strategies on Monthly Teleconferences and Annual Team Meetings			X			X		X	X	X	X	
Write, Submit Manuscript on Community-Academic Partnerships: Latino Health							X	X				
Prepare for Final Team Meeting; Invite other Interested Stakeholders to Attend										X	X	
Data QA Checks			X			X		X		X		X
Prepare and Analyze RCT Data								X	X	X	X	
Write RCT Manuscript (Submit 5/16)											X	X
Submit Year 3 Report and Final Study Protocol to PCORI												X

[a]Team Meetings will include community partners, researchers, Advisory Team members and patient advocates. These groups are representative of patient, caregiver, provider, stakeholder and researcher perspectives.
[b]The GUMC PI and specific Co-Investigators, along with each Site PI and Project Director and key interventionists will lead / participate in the interventionist training. For cost reasons, not all of the CA study team will attend the training in NY. The CA Site PI will travel to the NY training.
[c]We will follow-up the in-person interventionist training in NY with training of CA personnel. Trainers will be the same for each session and training will follow a manual.
[d]Assessments will be conducted using the PROMIS Assessment Center and computerized-adaptive testing technology. Our team has experience with the programming and use of the Assessment Center for development of study-specific assessments that include PROMIS items.

APPENDIX

Appendix A. Example PCI Survivor Session: Communication

The information below is based on the intervention delivered by Nueva Vida and also adapted from the Nuevo Amancer intervention developed by Dr. Anna Nápoles (Consultant) that is currently being implemented with women recruited through Latinas Contra Cancer in San Jose, CA. Intervention content is based on tenets of improving self-efficacy, communication and social support as guided by Social Cognitive Theory. Sessions are delivered in Spanish by trained Spanish monolingual or Spanish/English bilingual and bicultural interventionists.

Overview:

In this section we will learn about how cancer may affect you, your caregiver, other family and friends and how you communicate with one another. Good communication can help keep your relationships strong and healthy!

What we will do:

Today we will talk about some things you can do to keep good communication. We will discuss and practice how to express your feelings and what you need in a way that is respectful to you and to others. We will also talk about asking for help, which is not always easy when we are the ones to usually take care of things!

Core Learning Questions:

- How do I talk to my family about my cancer?
- How do I express my feelings and needs in a way that is respectful?
- How do I get the support I need to cope with my cancer and treatment?

Activities for Communication Session:

- Activity 1 Practicing Good Communication Skills
- Activity 2 People in My Life and the Ways They Support Me

CANCER AND YOUR FAMILY

A diagnosis of cancer affects the entire family, and they may feel many of the same emotions (fear, panic, anger, sadness, depression) as the person diagnosed with cancer. Many changes can take place. Some changes may be difficult, and some may be positive. For example:

- Roles and responsibilities within the family may change.
- Those who provide a steady income for their families may face economic problems.

- Some family members may resent the way in which breast cancer has changed their lives, or some family members may realize that they cannot take you or their own health for granted in the future.
- Older children may have to leave school to work to help the family.
- Some family members may feel unsure about how to help and what to say.
- Some survivors may not want to cause worry in their caregiver or their family by talking about their feelings or thoughts about cancer.
- An illness can increase tension and conflicts that may have existed prior to the diagnosis, or sometimes an illness can bring family members closer together.
- Having sexual relations with your partner may become difficult, or some partners grow closer with increased communication.

NOTE TO INTERVENTIONIST
Ask the survivors how their diagnoses have affected their families. For survivors with children, ask about their ages (review sections that apply).

How has your diagnosis affected your family or husband/partner?

Children
Children have different verbal skills and different abilities to understand concepts, such as illness, depending on their age. For example, a child who is 5 years old will have difficulty understanding how long a week or a month is. On the other hand, older children or teenagers who have a good understanding of these concepts will feel talked down to if they are not provided with the information they need to understand what is going on in their family.

Young children

Children as young as 2 feel the impact of a cancer diagnosis. Many times parents will try to protect their children by not talking about their illness. However, even young children will sense that something in the home has changed. Additionally, young children go through a period in which they feel responsible for everything that happens around them. It is therefore important for parents to reassure their children that their illness is not their fault.

A mother knows her children better than anyone else, and can better judge if there are drastic changes in her child. The following are changes to look out for in young children:

- Bed-wetting or thumb sucking when they have outgrown these behaviors
- Hitting their brothers or sisters or aggression toward classmates
- Nightmares or problems sleeping
- Over-clinging to mother
- Sadness, being withdrawn
- Drastic changes in appetite

Teenagers

Adolescence is a critical time in a teenager's development and support is vital to help them adjust. Although teens go through a phase where they need to be more independent, they still have a very strong need to feel safe within their family. Therefore, teens may have a more complicated emotional reaction to a parent's illness. The following are changes to look for in teens:

- Changes in school performance (drop in grades)
- Skipping school
- Substance abuse (alcohol or drugs)
- Anger
- Depression

How you can help your children

Although it may seem difficult, you need to talk openly with your children about your cancer. Here are some things you can do to help your children deal with your illness.

- Talk openly to your children in language they understand.
- Prepare your children for physical changes that may occur because of your cancer treatment such as hair loss, weight loss, or fatigue.
- You can increase the psychological well-being of your children by increasing your own.
- Try to maintain the family's normal routine.
- If you see extreme changes in behaviors, consult an expert who has experience in working with children.

NOTE TO INTERVENTIONIST
Ask the survivors to talk about a few of the ways they can help their family and communicate with them.

What are some ways you can help your family?

Other family members and close friends

Other family members, like siblings, parents, cousins and even close friends are also affected by your cancer diagnosis. They may be upset and concerned about your health and if you will get better. They may also want to help but be unsure of the best way how. For you, it may be difficult to talk with others in your family or your close friends for fear of worrying them too much or feeling like you need to stay strong for them. Some survivors may not want to show their emotions to others about something so personal like breast cancer. You may want to be able to do the same things as always—and perhaps for you that meant being the one who took care of others. These changes can be hard for everyone, but there are ways to make it easier to talk about difficult topics (see section 5.4).

Husbands or partners

Treatment for breast cancer may result in changes in your body. Unpleasant side effects because of a mastectomy, lumpectomy or chemotherapy can be difficult. These side effects can change how you feel physically and emotionally. Some of these side effects may include hair loss, breast removal, depression, or loss of sexual urge. Women may feel less feminine and less attractive. Women with partners or spouses may worry that their partner may no longer find them attractive or that their partner will leave them if they are not interested in sexual intimacy. Sometimes these feelings are difficult to talk about with your partner. Sometimes, partners do not want you to talk about your illness to other people or even to other family members.

Are you worried about how your body may change because of your cancer treatments?

Examples: I worry about…

- Gaining or losing weight
- Having one or both breasts removed
- Scarring – feeling disfigured
- Feeling less like a woman
- My hair not coming back in the same way

What feelings do you have related to the changes in your body?

Examples

- None
- I feel depressed about my hair loss
- I feel less of a woman without one (two) breasts
- I don't feel attractive anymore
- I worry my partner will not find me attractive
- I've lost my sexual urge
- I worry that I will not find someone who will find me attractive

What are some things that you like about yourself? Are there any areas of your life that are not impacted by your cancer diagnosis and treatment?

How you can help your partner

Miscommunication with our partners can lead to misunderstandings and resentments. Partners who feel they do not know what to say often stop communicating altogether or keep their distance. Some women may interpret their partner's silence as being insensitive and non-supportive. They may worry that their partner no longer finds them attractive, or that they have to be intimate with their partner just to maintain the relationship. Here are some tips on how to communicate with your partner:

- Create a safe space. Make sure the place you choose for your talk is private.
- Pick a time to talk when you and your partner are not stressed out, exhausted and won't be interrupted by phone calls or children.
- Don't talk about your feeling before, during or after having sexual relations.
- Discuss fears of rejection with your partner.
- Set aside some special time for just the two of you.
- Talk about ways to put more fun into your sexual relations.

- Help each other understand what you do and do not enjoy. If you just want to kiss, hug and cuddle without sexual relations, let your partner know. There are many ways to feel close and connected.
- If you feel your relationship is in trouble, talk openly about the problems that exist rather than pretending everything is fine.

5.4. THE IMPORTANCE OF EFFECTIVE COMMUNICATION

Remember that during your cancer treatment, you may not be able to take care of everyone else like you usually do. If you hold in all your questions and worries to protect the ones you love, you may feel more depressed and anxious. The sooner you are better, the sooner you will be able to go back to your normal activities.

You have a right to your feelings and a right to talk about them. You also have a right to ask for help when you need it. Below are some suggestions that may help you communicate better with others:

- **Stay calm:** Try to remain calm so that you do not forget what you want to say.
- **Maintain eye contact:** Look into their face to get their attention. They may not take you seriously or they might stop listening if you are looking in another direction.
- **Use a clear voice:** Speak in a tone of voice that is clear and firm. If you speak too softly or shout and yell the person will stop listening.
- **Learn how to express your feelings:** Express your feelings using "I" statements and avoid using "you" statements. The following statement can help you when talking about your feelings.

  "I am worried about____. I would like to talk with you about this. I feel____ when you____. I'd prefer if____."

- **Learn to say "no":** Sometimes we have a difficult time saying "no" to our loved ones and friends. We may feel guilty because we are unable to do what we usually do. During your cancer treatment, it is important not to push yourself beyond your physical or emotional limits.

  Example: *I feel badly that I cannot play with you today, but I am not feeling well now. Please play with your aunt. We can play in a few days when I'm feeling better.*

- **Ask others for help when you need it:** If you need help with housework, cooking or taking care of your children, it is important to ask for help from your partner, mother, sister, aunt, or friend.

  Example: *I feel badly that I am unable to cook the first few days after my chemotherapy. Can you cook today or ask your mother to cook on the days after my treatment?*

NOTE TO INTERVENTIONIST
Next you will help the survivors practice their communication skills. Take out Activity 5.1 "Practicing Good Communication Skills." Ask them to talk about a situation in which they had trouble communicating their concerns or needs related to their cancer with one of their family members.

We will now have you practice your communication skills. Take out Activity 5.1 "Practicing Good Communication Skills." Now think of a situation in which you had trouble communicating your concerns or needs related to your cancer with one of your family members. Answer the following questions about that situation. I will help you by writing down your answers for you if you like.

Activity 5.1 Practicing Good Communication Skills

Instructions: Think of a situation in which you had trouble communicating your concerns or needs related to your cancer with one of your family members. Answer the following questions about that situation.

1. Describe a situation in which you have had thoughts or concerns about your cancer that you would like to share with one of your family members, but have had trouble doing that.
   _____
   _____
2. How might you start the conversation with them?
   _____
   _____
3. List the positive and negative things that might happen if you share this with others.
   _____
   _____
   _____
4. After you talk with the other person, list the positive and negative things that actually happened.
   _____
   _____
   _____

Talking about cancer with my family

NOTE TO INTERVENTIONIST
Have the survivors role play the situation that they described in Activity 5.1 "Practicing Good Communication Skills." Give her positive feedback for following the communication tips in this section (stay calm, clear voice).

How to deal with criticism

No one likes to be criticized, but it happens. At one time or another, a family member or friend will criticize us either fairly or unfairly. The following are things that you can do that may help you when someone criticizes you:

- Listen objectively to what they have to say
- Stay relaxed. Take deep breaths
- Decide whether the criticism is justified or not
- Summarize what you have heard to be sure you understand
- Tell them you would like to think about it and discuss it at a later time
- Ask for specific examples of the behavior which is being criticized
- Ask for suggestions in how to change the behavior if you feel they are right
- If you disagree, tell them you respect their opinion, but don't agree

NOTE TO INTERVENTIONST
Ask the survivors if they remember a recent time when they felt they were being criticized. Practice with them how they might tell the person they disagrees in a respectful way.

Example

- If you agree, you can say, "Yes, I do that sometimes."
- If you disagree, you can say, "No, I don't agree that I am taking advantage of my illness."

Remember by expressing what you want and how you feel in a respectful way, you can improve your relationships with others.

5.5. GETTING THE SUPPORT YOU NEED

We all need support from others. Support can come from family, friends, neighbors, co-workers, support groups, spiritual leaders and/or healthcare providers. In general, the stronger your support system, the better you will be able to face tough situations and address any problems.

NOTE TO INTERVENTIONIST
For Activity 5.3 "People in My Life and the Ways They Support Me" you will ask the survivor to identify their sources of support (people) for each square. It's ok to have the same person in more than one square.

Who are the people who give you support and help you when you have problems?

To help you identify sources of support that you may not have thought about, we will do an activity together.

Activity 5.3 People in My Life and the Ways They Support Me

INSTRUCTIONS: Each square is for a different type of support that people can give you. Think about the people who fit each square and write their names in the square. The same person can be written in more than one square.

PRACTICAL SUPPORT Who will you ask to: - drive you to the hospital? - call to help you with chores? _____ _____ _____	**ADVICE OR INFORMATION** Who will you ask for advice/information - when you don't feel well? - when you don't understand how to do something? _____ _____ _____
COMPANIONSHIP Who will: - walk around the park with you? - spend the afternoon with you? _____ _____ _____	**EMOTIONAL SUPPORT** Who will you look to for: - encouragement? - help you when you are feeling down? _____ _____ _____

5.6. RECAP

Thank you for continuing with the program. It is very important that you finish the whole program. Let's briefly go over what we have covered this section.

- Do you remember some of the ways you can help your family deal with your illness?
- What are some good tips for expressing your feelings to others?
- Who can you ask for help when you need it?

Example PCI Caregiver Session: Communication

Overview:

In this section we will learn about how cancer may affect you, the person you are caring for, other family and friends and how you communicate with one another. Good communication can help keep your relationships strong and healthy!

What we will do:

Today we will talk about some things you can do to keep good communication. We will discuss and practice how to express your feelings and what you need in a way that is respectful to you and to others. We will also talk about asking for help, which is not always easy when we are the ones to usually take care of things!

Core Learning Questions:

- How do I talk to the person I'm caring for about her cancer?
- How do I express my feelings and needs in a way that is respectful?
- How do I get the support I need to cope with my caregiving responsibilities?

Activities for Communication Session:

- Activity 1 Practicing Good Communication Skills
- Activity 2 People in My Life and the Ways They Support Me

CANCER AND YOUR FAMILY

A diagnosis of cancer affects the entire family, and they may feel many of the same emotions (fear, panic, anger, sadness, depression) as the person diagnosed with cancer. Many changes can take place. Some changes may be difficult, and some may be positive. For example:

- Roles and responsibilities within the family may change.
- Those who provide a steady income for their families may face economic problems.
- Some family members may resent the way in which breast cancer has changed their lives, or some family members may realize that they cannot take their family member's or their own health for granted in the future.
- Older children may have to leave school to work to help the family.
- Some family members may feel unsure about how to help and what to say.
- Some survivors may not want to cause worry in their caregiver or their family by talking about their feelings or thoughts about cancer.

- Some caregivers may themselves feel tired or over stressed but may not want to share these feelings with the survivor for fear of making her feel bad.
- An illness can increase tension and conflicts that may have existed prior to the diagnosis, or sometimes an illness can bring family members closer together.
- Some couples may have difficulties with sexual intimacy while others grow closer with increased communication. For male caregivers, there may be concern over whether they will still be attracted to their partners after her breast cancer treatment.

NOTE TO INTERVENTIONIST
Ask the caregivers how their family member or friend's diagnoses have affected their families. For families with children, ask about their ages (and review sections that apply).

How has your friend/family member's diagnosis affected her family or husband/partner?

Children
Children have different verbal skills and different abilities to understand concepts, such as illness, depending on their age. For example, a child who is 5 years old will have difficulty understanding how long a week or a month is. On the other hand, older children or teenagers who have a good understanding of these concepts will feel talked down to if they are not provided with the information they need to understand what is going on in their family.

Young children

Children as young as 2 feel the impact of a cancer diagnosis. Many times parents will try to protect their children by not talking about their illness. However, even young children will sense that something in the home has changed. Additionally, young children go through a period in which they feel responsible for everything that happens around them. It is therefore important for parents to reassure their children that their illness is not their fault.

A parent knows their children better than anyone else, and can better judge if there are drastic changes in the child. The following are changes to look out for in young children:

- Bed-wetting or thumb sucking when they have outgrown these behaviors
- Hitting their brothers or sisters or aggression toward classmates
- Nightmares or problems sleeping
- Over-clinging to mother
- Sadness, being withdrawn
- Drastic changes in appetite

Teenagers

Adolescence is a critical time in a teenager's development and support is vital to help them adjust. Although teens go through a phase where they need to be more independent, they still have a very strong need to feel safe within their family. Therefore, teens may have a more complicated emotional reaction to a parent's illness. The following are changes to look for in teens:

- Changes in school performance (drop in grades)
- Skipping school
- Substance abuse (alcohol or drugs)
- Anger
- Depression

How you can help her/your children

Although it may seem difficult, you need to talk openly with the children about your friend/family member's cancer. Here are some things you can do to help her/your children deal with her illness.

- Talk openly to the children in language they understand.
- Prepare the children for physical changes that may occur because of cancer treatment such as hair loss, weight loss, or fatigue.
- You can increase the psychological well-being of the children by increasing your own.
- Try to maintain the family's normal routine.
- If you see extreme changes in behaviors, consult an expert who has experience in working with children.

NOTE TO INTERVENTIONIST
Ask the caregiver to talk about a few of the ways they can help the family and communicate with them.

What are some ways you can help her/your family?

Other family members and close friends

Other family members, like siblings, parents, cousins and even close friends are also affected by the survivor's cancer diagnosis. You may be upset and concerned about the survivor's health and if she will get better. You may also want to help but be unsure of the best way how. It may be difficult for you to talk with the survivor or others in your family for fear of causing more worry. You may be taking on some of the tasks or roles that the survivor had before, or you may feel like you need to be the strong person in the family. You may not want to show your emotions to others – or you may not want the survivor to share her emotions or tell others about her

cancer since it is so personal. These changes can be hard for everyone, but there are ways to make it easier to talk about difficult topics (see section 5.4).

Husbands or partners

Treatment for breast cancer may result in changes in your partner's body. Unpleasant side effects because of a mastectomy, lumpectomy or chemotherapy can be difficult. These side effects can change how she feels physically and emotionally. Some of these side effects may include hair loss, breast removal, depression, or loss of sexual urge. Women may feel less feminine and less attractive. Sometimes these feelings are difficult for her to talk about with you. Sometimes, you may not want her to talk about her illness to other people or even to other family members.

Are you worried about how your partner's body may change because of her cancer treatments?

Examples: I worry that she will…

- Gain or lose weight
- Have one or both breasts removed
- Have a scar
- Not be attractive to me
- Lose all of her hair or not have her hair grow back the same way

What feelings do you have related to the changes in her body?

Examples

- None
- I feel depressed about her hair loss
- I feel she is less of a woman without one (two) breasts
- I don't feel attracted to her anymore
- I've lost my sexual urge

How you can help your partner

Miscommunication with our partners can lead to misunderstandings and resentments. Partners who feel they do not know what to say often stop communicating altogether or keep their distance. Some women may interpret their partner's silence as being insensitive and non-supportive. Here are some tips on how to communicate with your partner:

- Create a safe space. Make sure the place you choose for your talk is private.
- Pick a time to talk when you and your partner are <u>not</u> stressed out, exhausted and won't be interrupted by phone calls or children.
- Don't talk about your feeling before, during or after having sexual relations.
- Discuss fears of rejection with your partner.

- Set aside some special time for just the two of you.
- Talk about ways to put more fun into your sexual relations.
- Help each other understand what you do and do not enjoy. If you just want to kiss, hug and cuddle without sexual relations, let your partner know. There are many ways to feel close and connected.
- If you feel your relationship is in trouble, talk openly about the problems that exist rather than pretending everything is fine.

5.4. THE IMPORTANCE OF EFFECTIVE COMMUNICATION

You have a right to your feelings and a right to talk about them. You also have a right to ask for help from others when you need it. Below are some suggestions that may help you communicate better with others:

- **Stay calm:** Try to remain calm so that you do not forget what you want to say.
- **Maintain eye contact:** Look into their face to get their attention. They may not take you seriously or they might stop listening if you are looking in another direction.
- **Use a clear voice:** Speak in a tone of voice that is clear and firm. If you speak too softly or shout and yell the person will stop listening.
- **Learn how to express your feelings:** Express your feelings using "I" statements and avoid using "you" statements. The following statement can help you when talking about your feelings.

  "I am worried about____. I would like to talk with you about this. I feel____ when you____. I'd prefer if____."

- **Learn to say "no":** Sometimes we have a difficult time saying "no" to our loved ones and friends. We may feel guilty because we are unable to do what we usually do. Caregiving is a difficult job and it is important not to push yourself beyond your physical or emotional limits.

  Example: *I feel badly that I cannot get together with you today, but I am very busy with other responsibilities. We can get together in a couple of weeks when things have calmed down.*

- **Ask others for help when you need it:** If you need help with housework, cooking or taking care of your children, it is important to ask for help from your family or friends.

NOTE TO INTERVENTIONIST

Next you will help the caregiver practice his/her communication skills. Take out Activity 5.1 "Practicing Good Communication Skills." Ask him/her to talk about a situation in which he/she had trouble communicating his/her concerns or needs related to his/her caregiving with one of her family members or friends. Help him/her by writing down his/her answers for him/her.

We will now have you practice your communication skills. Take out Activity 5.1. Think of a situation in which you had trouble communicating your concerns or needs to someone. Answer the following questions about that situation.

Activity 5.1 Practicing Good Communication Skills

Instructions: Think of a situation in which you had trouble communicating your concerns or needs related to your cancer with one of your family members. Answer the following questions about that situation.

- Describe a situation in which you have had thoughts or concerns about your cancer that you would like to share with one of your family members, but have had trouble doing that.

  _____
  _____

- How might you start the conversation with them?

  _____
  _____

- List the positive and negative things that might happen if you share this with others.

  _____
  _____
  _____

- After you talk with the other person, list the positive and negative things that actually happened.

  _____
  _____
  _____

Talking about cancer with my family/friends

NOTE TO INTERVENTIONIST
Have the caregivers role play the situations that they described in Activity 5.1 "Practicing Good Communication Skills." Give positive feedback for following the communication tips you in this section (stay calm, clear voice).

How to deal with criticism

No one likes to be criticized, but it happens. At one time or another, a family member or friend will criticize us either fairly or unfairly. The following are things that you can do that may help you when someone criticizes you:

- Listen objectively to what they have to say
- Stay relaxed. Take deep breaths
- Decide whether the criticism is justified or not
- Summarize what you have heard to be sure you understand
- Tell them you would like to think about it and discuss it at a later time
- Ask for specific examples of the behavior which is being criticized
- Ask for suggestions in how to change the behavior if you feel they are right
- If you disagree, tell them you respect their opinion, but don't agree

NOTE TO INTERVENTIONST
Ask the caregivers if they remember a recent time when they felt they were being criticized. Practice how they might respond.

Example

- If you agree, you can say, "Yes, I do that sometimes."
- If you disagree, you can say, "No, I don't agree that I am not doing enough to help.

Remember by expressing what you want and how you feel in a respectful way, you can improve your relationships with others.

5.5. GETTING THE SUPPORT YOU NEED

We all need support from others. Support can come from family, friends, neighbors, co-workers, support groups, spiritual leaders and/or healthcare providers. In general, the stronger your support system, the better you will be able to face tough situations and address any problems.

NOTE TO INTERVENTIONIST
For Activity 5.3 "People in My Life and the Ways They Support Me" you will ask the caregivers to identify their sources of support (people) for each square. It's ok to have the same person in more than one square.

Who are the people who give you support and help you when you have problems?

To help you identify sources of support that you may not have thought about, we will do an activity together.

Activity 5.3 People in My Life and the Ways They Support Me

INSTRUCTIONS: Each square is for a different type of support that people can give you. Think about the people who fit each square and write their names in the square. The same person can be written in more than one square.

PRACTICAL SUPPORT Who will you ask to: - help with getting the survivor to the hospital? - call to help you with chores? _____ _____ _____	**ADVICE OR INFORMATION** Who will you ask for advice/information - when you feel overwhelmed? - when you don't understand how to do something? _____ _____ _____
COMPANIONSHIP Who will: - walk around the park with you? - spend the afternoon with you? _____ _____ _____	**EMOTIONAL SUPPORT** Who will you look to for: - encouragement? - help you when you are feeling down? _____ _____ _____

5.6. RECAP AND SCHEDULE NEXT SESSION

Thank you for continuing with the program. It is very important that you finish the whole program. Let's briefly go over what we have covered this section.

- Do you remember some of the ways you can help your family/friends deal with your family member/friend's illness?
- What are some good tips for expressing your feelings to others?
- Who can you ask for help when you need it?

Appendix B: Draft Qualitative Interview Guide

Conducted in person or by telephone by trained bilingual and bicultural interviewer. Guide will be refined at initial team meeting with input from all team members.

Qualitative Interview with Survivor-Caregiver Dyads

Thank you again for being a part of this study. I will begin today by talking with you both individually and then we will complete a joint interview together.

Please remember that you can skip any question you do not want to answer. Also, I would like to tape record this interview to help us get down everything that you say. Only an ID number will be associated with this information. After we are done getting down the comments today, we will destroy this tape.

Is it ok to tape our interview now? ____ Yes
____ No (can still proceed, but without taping interview)

Thanks, ok, let's begin.

First, I will start with the individual interview with the survivor (have caregiver go into another room or get off of the telephone).

1. When you think about your diagnosis of cancer, what comes to mind as being most important for your current health? Why?
    a. Probe: Mental Health? Physical Health? Spiritual Health?
2. When you think about the people in your life, who do you turn to when you want to talk about things? Who provides you with help? What type of help do they provide? What type of support has been most helpful for you?
    a. Probe: Emotional support? Help getting places, groceries, cleaning etc (instrumental support)?
3. In what ways, if any, has your relationship with [Caregiver's name] changed since you were diagnosed?
    a. Probe: Tell me what is the same about how you two talk now? Tell me what is different about how you two talk now?
    b. How deeply are you able to share your feelings and thoughts about things going on in your life with [Caregiver's name]?
4. How has your level of stress been since your diagnosis / treatment? What things do you do to help you feel better? What happens in your life to make things worse?

Thank you so much for sharing your thoughts and feelings. I will now conduct the individual interview with [Caregiver's name] (have survivor leave room or get off of the telephone). After that is completed, we will complete a joint interview with both of you.

1. When you think about <u>your</u> current health, what factors come to mind as being most important? Why?
    a. Probe: Mental Health? Physical Health? Spiritual Health?
2. When you think about the people in your life, who do you turn to when you want to talk about things? Who provides you with help? What type of help do they provide? What type of support has been most helpful for you?
    a. Probe: Emotional support? Help with getting places, grocers, etc (instrumental support)?
3. In what ways, if any, has your relationship with [Survivor's name] changed since she was diagnosed?

   a. Probe: Tell me what is the same about how you two talk now? Tell me what is different about how you two talk now?
   b. How deeply are you able to share your feelings and thoughts about things going on in your life with [Survivor's name]?
4. How has your level of stress been since [Survivor's name] diagnosis / treatment? What things do you do to help you cope? What happens in your life to make things worse?

Thank you so much for sharing your thoughts and feelings (bring survivor back into the room or have her get back on the telephone).

Great, I will now conduct the joint interview with both of you.

1. What has been most helpful for both of you in coping with [Survivor's name] diagnosis and treatment?
   a. Probe: Treatment and support from doctors? Support from family and friends? Support from colleagues? Faith or religious community?
2. Tell me your thoughts about talking with doctors about [Survivor's name] diagnosis and treatment.
   a. Probe: What information was easy to understand? What information was hard to understand? Was there anything you found particularly helpful or confusing?
3. Tell me about the sources of support that have been most helpful to you.
   a. Probe: Patient advocate or navigator? Nurses or doctors? Support group? Family or friends? Colleagues? Faith or religious community?
4. To the caregiver: What would you want to tell other Latina women who get diagnosed with breast cancer?
5. To the survivor: What would you want to tell other caregivers for Latina breast cancer survivors?
6. For both: Share with me how cancer has impacted your relationship.
7. Now I would briefly like to show you [read to you] a list of topics we are thinking about for a program to help Latina breast cancer survivors and their caregivers. As you look through [listen], I would like for you to think about if there are any other topics that might be helpful for us to include in the program.
   1. The impact of cancer in the family
   2. Stress management
   3. Anger management
   4. Improving communication: family, friends, providers
   5. Intimacy after cancer: emotional and sexual
   6. Spirituality and cancer
   7. Balancing emotional and physical needs
   8. Role changes
   9. End of life issues (putting our lives in order)
   10. Understanding distress
   11. Including others in helping caregivers
8. Are there topics we have left out?
9. What topics do you think would be most important to you [read list again as needed].

Those are all of my questions. Do you have any other comments or questions for me that you would like to share? Any feedback on how we can better support Latina breast cancer survivors and their caregivers?

Thank you again for your time and participation. As a small thank you, we do provide a $20 gift card in appreciation of your time. Would you prefer one for Safeway Foods (or local store), Amazon or Target?

Appendix C: Treatment Fidelity Plan

STRATEGIES TO ENHANCE TREATMENT FIDELITY

Design of Study	Goal	Strategies for Implementation
	Monitor treatment dose for survivors in PCI and UC conditions.	Trained interventionists will follow manualized treatment protocols for PCI and will complete quality assessment forms following each session. Length of session and number of attendees at each session will be tracked for all participants. Trained study personnel will closely monitor use of any support services by UC survivors and UC caregivers. We will also track usage of any support services or programs through study assessments.
	Plan for implementation setbacks.	Identify experienced bilingual and bi-cultural individuals who can be trained as needed if one of the study interventionists becomes unavailable. Additional training resources to be provided by institutional support from GUMC as needed. This plan will ensure adequate interventionist training and coverage.
Monitoring and Improving Interventionist Training	Goal	Strategies for Implementation
	Standardize training.	Conduct training in-person at the same time. The 2-day training session will include a study overview and mock sessions with interventionists. GU PI and Co-Investigators and Site PIs will observe and provide feedback of mock training sessions, with input from co-investigators and consultants. Training will use standardized training manuals for all research personnel.
	Ensure interventionist skill acquisition.	Interventionists will complete two mock sessions during training. Sessions will be scored for adherence according to an a priori checklist. Intervention delivery checklists will be reviewed by team investigators at weekly team meetings.
	Minimize “drift” in interventionists’ skills.	Conduct annual booster training sessions to review interventionist identified problems and review protocol. Conduct weekly meetings with research staff.
	Accommodate team members’ differences.	Evaluate effectiveness of assessment interviews of research assistants via periodic monitoring of telephone interviews. Provide intensive training to all study personnel according to needs, background, or clinical experience. Review interventionist experiences in team meetings and address as needed.

Monitoring and Improving Delivery of Treatment	Goal	Strategies for Implementation
	Control for interventionists' differences.	Assess participants' perceptions of interventionists' warmth and credibility via self-report satisfaction questionnaire and provide feedback to interventionists. Include in analyses if appropriate. Monitor participant complaints. Have different co-investigators evaluate session notes and intervention delivery checklists.
	Reduce differences within treatment.	Use treatment manual and handouts for PCI condition.
	Ensure adherence to treatment protocol.	Interventionists will complete a checklist of intervention components delivered after each session for all groups.
	Minimize contamination between conditions.	Emphasize in training sessions the rationale for keeping conditions separate. As survivors and caregivers in the UC condition are not exposed to in any way to manualized group sessions, contamination concerns are lessened. We will track usage of other support programs by all participants.
Monitoring and Improving Receipt of Treatment	Goal	Strategies for Implementation
	Ensure participant comprehension.	Assess skills and functioning at baseline (e.g., self-efficacy for communication, social support, distress). Intervention includes the practice of skills and behavioral strategies within each group session. Have interventionist ask questions/use prompts that ask participants to paraphrase/summarize content. Record interventionists' perceptions of participant understanding after each session.
	Maximize participant ability to use skills.	Measure mediating variables immediately post-intervention and 6-months post intervention. Ask participants to provide feedback on their ability to understand and use materials.
Monitoring and Improving Enactment of Treatment Skills	Goal	Strategies for Implementation
	Ensure participant ability to perform behavioral skills.	Monitor homework completion and engagement in session discussion.

Strategies adapted from recommendations provided in Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, Ogedegbe G, Orwig D, Ernst D, Czajkowski S, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol* 2004;23(5):443-451. PMID:15367063.

Appendix D: Draft Baseline Interview

INSTRUCTIONS READ BY RESEARCH ASSISTANT: This questionnaire is for Latina Breast Cancer survivors and their caregivers. Remember that you can skip any question you do not want to answer. We will not have your name or information with your responses. There are no right or wrong answers. Thank you.

SECTION A: BREAST CANCER MEDICAL QUESTIONS – Survivors Only

When you were diagnosed with breast cancer, and where did you live at the time of diagnosis?

Date _____/ _____ State and Country _____
Month / Year

How old were you when you were diagnosed? _____ years

Please choose one response, indicating, Yes or No.				
Was your cancer bilateral (in both breasts)?	Yes	No	Unsure	N/A
Do you remember the grade or stage of your cancer when it was diagnosed? (Grade 0, 1, 2, 3, 4 / Stage 0, I, II, III, IV) If Yes, what grade or stage was the cancer at the time of diagnosis ?_____	Yes	No	Unsure	N/A
Did your cancer spread to your lymph nodes?	Yes	No	Unsure	N/A
Do you remember the size of your tumor? If Yes, what was the size of your tumor? ____	Yes	No	Unsure	N/A
Have you ever been diagnosed with breast cancer a second time? If Yes, how old were you at your 2nd diagnosis? _____ years Was this a recurrence of the original cancer or a new primary diagnosis? _____ Recurrence _____ New Primary _____ Don't know	Yes	No	Unsure	N/A
Have you had any other type of cancer? If Yes, please specify: _____	Yes	No	Unsure	N/A
Did you have radiation therapy for your breast cancer?	Yes	No	Unsure	N/A
Are you still receiving radiotherapy?	Yes	No	Unsure	N/A
Did you have chemotherapy for your breast cancer?	Yes	No	Unsure	N/A
Are you still receiving chemotherapy?	Yes	No	Unsure	N/A
Did you take any hormone treatment for your breast cancer (For example, Tamoxifen, Femara, Arimidex or Aromasin)? If Yes, for how long? _____ (months / years) If Yes, are you currently taking a hormone? _____ Yes ____ No Which one? _____ For how long? _____ (months / years)	Yes	No	Unsure	N/A

Had you had surgery to treat your breast cancer? Which type of surgery have you had? _____ Mastectomy _____ Bilateral Mastectomy _____ Lumpectomy	Yes	No	Unsure	N/A
Have you had reconstruction or plastic surgery? If Yes, what type of reconstruction? _____ Breast implants _____ Removed tissue from other part of your body (eg. tram flap) _____Other (Specify): _____	Yes	No	Unsure	N/A
Had you gone through menopause ("the change of life") before your diagnosis?	Yes	No	Unsure	N/A
Is mammography a source of stress for you?	Yes	No	Unsure	N/A
Are your regular appointments for your follow up a source of stress?	Yes	No	Unsure	N/A
Do your regular appointments for your follow up interfere with your usual daily activities?	Yes	No	Unsure	N/A
Do you experience side effects from your breast cancer treatment that interfere with your regular daily activities?	Yes	No	Unsure	N/A
Has your doctor made any specific recommendations regarding foods to eat?	Yes	No	Unsure	N/A
Has your doctor made any specific recommendations on exercising?	Yes	No	Unsure	N/A

SECTION B: MEDICAL HISTORY – Survivors and Caregivers

The next group of questions is about your medical history. I will read the list to you. Please indicate whether you have these problems, indicating yes or no as I read each one.

	Yes	No	Unsure
Arthritis (rheumatoid and osteoarthritis)			
Osteoporosis			
Asthma			
Chronic obstructive pulmonary disease (COPD), acquired respiratory distress syndrome (ARDS) or emphysema			
Angina			
Congestive heart failure (or heart disease)			
Heart attack (myocardial infarct)			
Neurological disease (such as multiple sclerosis or Parkinson's)			
Stroke or TIA			
Peripheral vascular disease			
Diabetes—types I and II			
Upper gastrointestinal disease (ulcer, hernia, reflux)			
Depression			
Anxiety or panic disorders			
Visual impairment (i.e. cataracts, glaucoma, macular degeneration)			
Hearing impairment (very hard of hearing, even with hearing aids)			
Degenerative disc disease (back disease, spinal stenosis or severe chronic back pain)			
Obesity and/or body mass index > 30			

SECTION C: ACCULTURATION – Survivors and Caregivers

We would like to ask you some questions about languages you speak. Please choose one response. I will read the question and then the answer choices.

	Only Spanish	More Spanish than English	Both Equally	More English than Spanish	Only English	Other?
In general, what language(s) do you read and speak?	1	2	3	4	5	6
What was the language(s) you used as a child	1	2	3	4	5	6
What language(s) do you usually speak at home?	1	2	3	4	5	6
In which language(s) do you usually think?	1	2	3	4	5	6
What language(s) do you usually speak with your friends?	1	2	3	4	5	6
In what language(s) are the T.V. and Radio programs you usually watch?	1	2	3	4	5	6

The next questions are about your friends. Please circle your answer.

	All Latinos/Hispanics	More Latinos than Americans	About Half & Half	More Americans than Latinos	All Americans	Other?
Your closest friends are	1	2	3	4	5	6
You prefer going to social gatherings/parties at which the people are	1	2	3	4	5	6
If you could choose your children's friends you would want them to be	1	2	3	4	5	6

SECTION D: COMMUNICATION WITH PROVIDERS—Survivors Only

Please rate the next items about the visits with your health care provider where you talked about your breast cancer treatment and survivorship care plans. Please choose one answer for each item and answer every question. There is no right or wrong answer; just tell us how you feel.

How was your health care provider at…	N/A	Poor	Fair	Good	Very Good	Excellent
Fully understanding your fears (telling you that he/she really understands your fears; not ignoring things)	☐	☐	☐	☐	☐	☐
Showing care and kindness (being truly interested; not being cold or uncaring)	☐	☐	☐	☐	☐	☐
Being positive (having a positive way of talking with you; a good attitude; being honest but not negative about your illness)	☐	☐	☐	☐	☐	☐
Telling you things clearly (fully understanding your questions, tell you things in a way you understand, giving you good and helpful information)	☐	☐	☐	☐	☐	☐
Helping you to take control (talking with you about what you can do to make your health better; being helpful and not scolding you)	☐	☐	☐	☐	☐	☐
Making a plan of action with you (talking about the options; including you in making choices as much as you want to be included; not ignoring your thoughts and feelings on things)	☐	☐	☐	☐	☐	☐
Helping you feel calm (friendly and warm to you, treating you with respect, not cold or rushed)	☐	☐	☐	☐	☐	☐
Letting you tell your story (letting you talk about your illness or fears, not interrupting you)	☐	☐	☐	☐	☐	☐
Really listening (paying close attention to you and what you were saying)	☐	☐	☐	☐	☐	☐
Being interested in you as a whole person (asking/knowing important details about your life and illness, you are not “just a number”)	☐	☐	☐	☐	☐	☐

SECTION E: SOCIAL SUPPORT – Survivors and Caregivers

I will read a list of things that other people do for us or give us that may be helpful or supportive. Please listen to each statement carefully and indicate an answer that is closest to your situation. Answering "1" would mean that you get that type of support "much less than you would like" and answering "5" would mean that you get that type of support "as much as you would like." Answer each item as best as you can. There are no rights or wrong answers.

	Much less than I would like				As much as I would like
I have people who care about what happens to me.	1	2	3	4	5
I get love and affection.	1	2	3	4	5
I get chances to talk to someone about problems at work or with my homework.	1	2	3	4	5
I get chances to talk to someone I trust about my personal and family problems.	1	2	3	4	5
I get chances to talk about money matters.	1	2	3	4	5
I get invitations to go out and do things with other people.	1	2	3	4	5
I get useful advice about important things in life.	1	2	3	4	5
I get help when I'm sick in bed.	1	2	3	4	5

SECTION F: SOCIAL CONSTRAINTS—Survivors Only

Sometimes, even when people have good intentions, they may say or do things that upset you. Think about the last two weeks and indicate how often the most important person in your life did the following things. Use the scale that ranges from: 1=Never, 2=Rarely, 3=Sometimes, 4=Often. Please circle only one response for each question.

	Never	Rarely	Sometimes	Often
How often did you feel that you had to keep your feelings about your breast cancer to yourself, because they made the most important person in your life feel uncomfortable?	1	2	3	4
How often when you talked about your breast cancer, did the most important person in your life give you the idea that he/she didn't want to hear about your cancer?	1	2	3	4
How often did the most important person in your life let you down by not showing you as much love and concern as you would have liked?	1	2	3	4
How often has the most important person in your life really got on your nerves?	1	2	3	4

In the previous questions can you tell me who did you rate as the most important person in your life?

___ A friend ____ Spouse ____ Mother ____ Father ____Sister _____ Other (Specify) _____

SECTION G: DYADIC COPING – Survivors and Caregivers

	Never true	Seldom true	Sometimes true	Often True	Always True
My family member is willing to listen to me when I just need to talk	☐	☐	☐	☐	☐
My family member gives me a great deal of affection and warmth.	☐	☐	☐	☐	☐
My family member ignores or makes light of my concerns.	☐	☐	☐	☐	☐
My family member supports me as I try to cope with the illness.	☐	☐	☐	☐	☐
When around my family member, I pretend things are going better than they really are.	☐	☐	☐	☐	☐
My family member and I work as a team to manage the effects of the illness.	☐	☐	☐	☐	☐
My family member gives me positive feedback for my attempts to cope with the illness.	☐	☐	☐	☐	☐

SECTION H: QUALITY OF LIFE (PROMIS) – Survivors and Caregivers

NOTE: These are sample items. Computerized Adaptive Testing (CAT) will generate the specific items for each participant based on their prior answers. This approach allows for the most precise estimates.

Global Health

Please respond to each item by choosing only one answer for each question.

	Completely	Mostly	Moderately	A Little	Not at All
To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	☐	☐	☐	☐	☐

Please indicate how true each statement has been for you during the past 7 days.

	Never	Rarely	Sometimes	Often	Always
How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	☐	☐	☐	☐	☐

	None	Mild	Moderate	Severe	Very Severe
How would you rate your fatigue on average?	☐	☐	☐	☐	☐

	No pain 0	1	2	3	4	5	6	7	8	9	Worst imaginable pain 10
How would you rate your pain on average?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Social Health

	Excellent	Very Good	Good	Fair	Poor
In general, would you say your health is:	☐	☐	☐	☐	☐
In general, would you say your quality of life is:	☐	☐	☐	☐	☐
In general, how would you rate your physical health?	☐	☐	☐	☐	☐
In general, how would you rate your mental health, including your mood and your ability to think?	☐	☐	☐	☐	☐
In general, how would you rate your satisfaction with your social activities and relationships?	☐	☐	☐	☐	☐
In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community and responsibilities as a parent, child, spouse, employee, friends, etc).	☐	☐	☐	☐	☐

Physical Health

The following questions ask about your ability to stand and move with and without support. "Support" means using items such as canes, walking sticks, walkers and leg braces, or other people.

Can you walk 25 feet on a level surface (with or without support)? Yes No

Yes→ Participant receives all items;

No→Participant skips to question "Are you able to wash and dry your body?

	Never	Rarely	Sometimes	Usually	Always
I have trouble doing all of my regular leisure activities with others	☐	☐	☐	☐	☐
I have trouble doing all of the family activities that I want to	☐	☐	☐	☐	☐
I have trouble doing all of my usual work (include work at home)	☐	☐	☐	☐	☐
I have trouble doing all of the activities with friends that I want to do	☐	☐	☐	☐	☐
I have to limit my regular activities with friends	☐	☐	☐	☐	☐
I have to limit my regular family activities	☐	☐	☐	☐	☐
I have trouble doing all of the work that is really important to me (include work at home)	☐	☐	☐	☐	☐

Physical Health, continued

	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
Are you able to walk a block on flat ground?	☐	☐	☐	☐	☐
Are you able to walk up and down two steps?	☐	☐	☐	☐	☐
Are you able to run at a fast pace for two miles?	☐	☐	☐	☐	☐
Are you able to do yard work like raking leaves, weeding, or pushing a lawn mower?	☐	☐	☐	☐	☐
	Not at all	Very little	Somewhat	Quite a lot	Cannot do
Does your health now limit you in doing strenuous activities such as backpacking, skiing, playing tennis, bicycling or jogging?	☐	☐	☐	☐	☐
	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
Are you able to wash and dry your body?	☐	☐	☐	☐	☐
Are you able to get in and out of bed?	☐	☐	☐	☐	☐
Are you able to bend down and pick up clothing from the floor?	☐	☐	☐	☐	☐
Are you able to push open a heavy door?	☐	☐	☐	☐	☐
Are you able to reach and get down an object (such as a can of soup) from above your head?	☐	☐	☐	☐	☐
Does your health now limit you in doing eight hours of physical labor?	☐	☐	☐	☐	☐

SECTION I: MENTAL HEALTH (BSI) – Survivors and Caregivers

Now I am going to read a list of problems and complaints that people sometimes have. Please tell me how much discomfort that problem has caused you in the last two weeks. Your answer choices are not at all, slightly, moderately or extremely.

	Not at All	Slightly	Moderately	Extremely
Nervousness or shakiness inside	1	2	3	4
Suddenly scared for no reason	1	2	3	4
Feeling lonely	1	2	3	4
Feeling fearful	1	2	3	4
Feeling blue	1	2	3	4
Feeling not interested in things	1	2	3	4
Feeling tense or keyed up	1	2	3	4
Spells of terror or panic	1	2	3	4
Feeling hopeless about the future	1	2	3	4
Feeling so restless you couldn't sit still	1	2	3	4
Feeling of worthlessness	1	2	3	4

SECTION J: CANCER RELATED DISTRESS – Survivors and Caregivers

I'm going to read a list of comments made by some people who have cancer in their family. Please tell me how frequently these comments were true for you **during the past seven days**. **[READ STATEMENT]** Would you say this occurred...not at all, rarely, sometimes, or often?

	Not at All	Rarely	Some-times	Often
I thought about it when I didn't mean to.....	0	1	3	5
I avoided letting myself get upset when I thought about it or was reminded of it.....	0	1	3	5
I had tried to remove it from memory.....	0	1	3	5
I had trouble falling asleep or staying sleep, because of pictures or thoughts about it that came into my mind	0	1	3	5
I had waves of strong feelings about it.....	0	1	3	5
I had dreams about it.....	0	1	3	5
I stayed away from reminders of it.....	0	1	3	5
I felt as if it hadn't happened or it wasn't real.....	0	1	3	5
I tried not to talk about it.....	0	1	3	5
Pictures about it popped into my mind.....	0	1	3	5
Other things kept making me think about it.....	0	1	3	5
I was aware that I still had a lot of feelings about it, but I didn't deal with them.....	0	1	3	5
I tried not to think about it.....	0	1	3	5
Any reminder brought back feelings about it.....	0	1	3	5
My feelings about it were kind of numb.....	0	1	3	5

SECTION K: STIGMA SCALE—Survivors Only

The following questions pertain to your feelings about your breast or mastectomy site. Please indicate the way each statement pertains to you personally. When answering consider how you felt over the **past month**. Using the scale below we would like for you to answer on a scale of 1 to 5, where 1 is never and 5 is always. Please circle only one answer for each question.

S: I avoid looking at my scars from breast surgery	Never	Almost never	Sometimes	Almost always	Always
I feel less feminine since cancer	Never	Almost never	Sometimes	Almost always	Always
I avoid physical intimacy	Never	Almost never	Sometimes	Almost always	Always
I feel part of me must remain hidden	Never	Almost never	Sometimes	Almost always	Always
I am afraid of touching the scars from breast surgery	Never	Almost never	Sometimes	Almost always	Always
I avoid close physical contact such as hugging	Never	Almost never	Sometimes	Almost always	Always
I would keep my chest covered during sexual intimacy	Never	Almost never	Sometimes	Almost always	Always
I feel sexually attractive when I am nude	Never	Almost never	Sometimes	Almost always	Always

SECTION L: MEDICAL EXPERIENCES – Survivors and Caregivers

Thinking about the relationship between race or ethnicity and the American medical system in general – not just specific to the care you received during your breast cancer experiences—please rate how strongly you agree or disagree with the following statements. Your answer choices are: strongly disagree, disagree, neutral, agree, strongly agree, unsure, or prefer not to answer.

People of my ethnic group cannot trust doctors and health care workers	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Unsure	Prefer not to answer
Doctors and health care workers treat people of my ethnic group like “guinea pigs”	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Unsure	Prefer not to answer
People of my ethnic group receive the same medical care from doctors and health care workers as people from other groups	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Unsure	Prefer not to answer
Doctors and health care workers do not take the medical complaints of people of my ethnic group seriously	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Unsure	Prefer not to answer
I have personally been treated poorly or unfairly by doctors or health care workers because of my ethnicity	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Unsure	Prefer not to answer
If you don’t speak English fluently you will not receive the same type of care that the people who speaks English well	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Unsure	Prefer not to answer

SECTION M: MEDICAL CARE EXPERIENCES – Survivors and Caregivers

In this section, we list some more things people said about medical care. I'd like to remind you that all of your answers are confidential and there are no right or wrong answers to any questions. We are interested in your opinion. We are interested in how good or bad you feel about the overall medical care you have received from the doctor you see the most often. For caregivers: If you have not received care recently, think about what you would expect if you needed care today. Please indicate how strongly you agree or disagree with each of the following statements. Please choose only one response option for each question.

Doctors are good about explaining the reasons for medical tests	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
I think my doctor's office has everything needed to provide complete medical care.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
The medical care I have been receiving is just about perfect.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
Sometimes doctors make me wonder if their diagnosis is correct.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
I feel confident that I can get the medical care I need without being set back financially.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
When I go for medical care, they are careful to check everything when treating and examining me.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
I have to pay for more of my medical care than I can afford.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
I have easy access to the medical specialists I need.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
Where I get medical care, people have to wait too long for emergency treatment.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
Doctors act too businesslike and impersonal toward me.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
My doctors treat me in a very friendly and courteous manner.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
Those who provide my medical care sometimes hurry too much when they treat me.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
Doctors sometimes ignore what I tell them.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
I find it hard to get an appointment for medical care right away.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
I am dissatisfied with some things about the medical care I receive.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
I am able to get medical care whenever I need it.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree

SECTION N: RCOPE – RELIGION AND SPIRITUALITY – Survivors and Caregivers

Think about how you try to understand and deal with the worst problems in your life. Please listen to the items below and think about whether these statements apply to you. Please choose only one answer to indicate how often you have done these things to understand or deal with the worst problems in your life.

I thought about how my life is part of a large spiritual force	Not at all	Somewhat	Quite a bit	A great deal
I worked together with God as partners to go through the difficult times	Not at all	Somewhat	Quite a bit	A great deal
I looked to God for strength, support, and guidance	Not at all	Somewhat	Quite a bit	A great deal
I felt that the stressful situations are a way for God to punish me for my sins or my lack of spirituality	Not at all	Somewhat	Quite a bit	A great deal
I wondered whether God had abandoned me	Not at all	Somewhat	Quite a bit	A great deal
I tried to make sense of the situation without relying on God	Not at all	Somewhat	Quite a bit	A great deal
Until what point does your religion play a role in understanding and deal with the stressful situations?	Not at all	Somewhat	Quite a bit	A great deal

SECTION O: THINKING BEYOND ONESELF - Survivors and Caregivers

The next few questions are about your thoughts and opinions about learning about cancer and its impact. I will read you the question and then the answer choices.

Learning about cancer and its impact is important for both my spouse and I.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
Whether my [name of other person's role: spouse/ partner/ sister/ mom/daughter] learns about cancer and its impact could affect my future too.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
If my [spouse/ partner/ sister/ mom/ daughter] plans to learn about cancer and its impact, I would say that is a good idea.	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
I can think of reasons learning about cancer and its impact is important to my [spouse/ partner/ sister/ mom/ daughter]	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree

SECTION P: COMMUNICATION SELF-EFFICACY—Survivors and Caregivers

The following questions ask about your communications with your caregiver. On a scale of 1 to 10, 1 meaning "not at all confident" and 9 meaning "totally confident", please tell me how confident you are that you can talk with your caregiver about the following things.

SURVIVORS: I am confident in my ability to…	How confident are you? 1 to 10	N/A
Talk with my caregiver about my cancer		
Talk with my caregiver about changes in my body due to treatment		
Talk with my caregiver (if a spouse or partner) about our sexual relationship		
Talk with my caregiver about my fears		
Talk with my caregiver about future appointments with my doctor		
Talk with my caregiver about getting a will or other end of life documents		
Talk with other members of my family about my breast cancer		
Talk with my caregiver to ask for extra help or support		

CAREGIVERS: I am confident in my ability to…	How confident are you? 1 to 10	N/A
Talk with the survivor about her cancer		
Talk with the survivor caregiver about changes in her body due to treatment		
Talk with the survivor (if a spouse or partner) about our sexual relationship		
Talk with the survivor about my own fears		
Talk with the survivor about future appointments with her doctors		
Talk with the survivor about getting a will or other end of life documents		
Talk with other members of my family about the survivor's breast cancer		
Talk with other members of my family to ask for extra help or support in providing care to the survivor.		

SECTION Q: CANCER BEHAVIOR INVENTORY (MERLUZZI)—Survivors

NOTE: We will adapt the following items based on experiences of Nueva Vida and Dr. Nápoles in administering these items to Latina survivors

The next questions are about things you might do when receiving treatment for cancer. On a scale of 1 to 9, 1 meaning "not at all confident" and 9 meaning "totally confident, please tell me how confident you are that you can accomplish each behavior.

	Not at all confident				Moderately confident				Totally confident
Maintaining independence.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Maintaining a positive attitude.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Accepting that I have cancer.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Maintaining work activity.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Asking nurses questions.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Remaining relaxed throughout treatments and not allowing scary thoughts.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Seeking support from people & groups outside the family.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Maintaining a daily routine.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Asking technologists questions.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Using denial. (Putting things out of my mind at times)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Remaining relaxed throughout treatment (chemotherapy, radiation).	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Coping with physical changes.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Ignoring things that cannot be death with.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Actively participating in treatment decisions.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Sharing feelings of concern..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Remaining relaxed while waiting at least one hour for my appointment.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Expressing personal feelings of anger or hostility.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Keeping busy with activities.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Finding an escape ("getting away from it all" at times).	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Reducing any anxiety with getting my blood drawn.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9

	Not at all confident				Moderately confident				Totally confident
Maintaining a sense of humor.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Accepting physical changes or limitations caused by cancer treatment.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Seeking consolation.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Reducing any nausea associated with treatment (chemotherapy, radiation).	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Maintaining hope.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Asking physicians questions.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Doing something, anything.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Managing pain.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Managing nausea and vomiting.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Controlling my negative feelings about cancer.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9

SECTION R: FAMILISM SCALE – Survivors and Caregivers

The following questions pertain to your perception of family support. Using the scale below, we would like for you to answer to the next statements on a scale of 1 to 10, where 1 is strongly disagree and 10 strongly agree.

	Strongly disagree									**Strongly agree**
A person should always live near his or her parents and spend time with them on a regular basis.	1	2	3	4	5	6	7	8	9	10
A person should always support members of the extended family, for example, aunts, uncles, and in-laws, if they are in need even it is a big sacrifice.	1	2	3	4	5	6	7	8	9	10
A person should rely on his or her family if the need arises	1	2	3	4	5	6	7	8	9	10
A person should often do activities with his or her immediate and extended families, for example, eat meals, play games, or go somewhere together.	1	2	3	4	5	6	7	8	9	10
A person should help his or her elderly parents in times of need, for example, helping financially or sharing a house.	1	2	3	4	5	6	7	8	9	10

SECTION S: CAREGIVER INVENTORY –Caregivers Only

The next questions are about things you might do when caring for a person with an illness. We are interested in how confident you are that you can do those things. Make sure your ratings reflect your confidence whether or not you have done these in the past. So, your rating should reflect your confidence that you could do these things in the future.. On a scale of 1 to 9, 1 meaning "not at all confident" and 9 meaning "totally confident, please tell me how confident you are that you can accomplish each behavior.

	Not at all confident				Moderately confident				Totally confident
Coping with information overload.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Listening and learning from the person as to how to care better for her.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Letting go of things I can't control.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Expressing negative feelings about the illness.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Maintaining hope.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Being able to notice the "good moments" in caregiving when they occur.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Allowing the person to have and express her own feelings.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Assisting the person with activities, such as feeding, washing, dressing or using the toilet.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Continuing to take care of yourself (for example: exercise, diet, sleep).	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Talking openly and honestly with the person.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Continuing to engage in personal activities that you like to do.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Talking about death and dying.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Providing emotional support to the person I'm caring for.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Understanding medical information from doctors, nurses or other sources.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Seeking support for yourself.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Dealing with feelings of helplessness.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Dealing with the person expressing negative feelings toward you when they occur.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Assisting and encouraging the person in following through with all treatments and taking all prescribed medications.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9

	Not at all confident				Moderately confident				Totally confident
Asking physicians and nurses questions.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Dealing with criticism from others.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9
Maintaining a close relationship with the person I'm caring for. .	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9

SECTION T: DEMOGRAPHICS

This is the last section. We have some questions about you. You can skip any question you do not wish to answer; however this information is important for our study.

What is your birth date? _____/_____/_____ (MM/DD/YY)

Which is your ethnicity? Please choose one answer.

Hispanic/Latino	1
Non-Hispanic/Latino	2

What is your race? I will read a list and please tell me which one best describes you.

	Check below
Black or African American	
White or Caucasian	
American Indian/Alaska Native	
Asian	
Native Hawaiian or other Pacific Islander	
More than One Race	
Don't Know/Unsure	
Prefer Not to Answer	

What is the highest grade or level of schooling you have completed? Have you completed…

	Check below		Check below
No formal schooling		11th grade	
1st grade		12th grade	
2nd grade		College 1 year	
3rd grade		College 2 years	
4th grade		College 3 years	
5th grade		College 4 years	
6th grade		College 5 years	
7th grade		College 6 years	
8th grade		Training after high school	
9th grade		Other. Specify: _____	
10th grade			

Where or in which country where you born? Were you born in….

	Check Below		Check Below
Argentina		México	
Bolivia		Nicaragua	
Brasil		Perú	
Colombia		Puerto Rico	
Chile		Republica Dominicana	
Ecuador		United States. Which generation you are (first, second, third?) Specify: _____	
El Salvador		Other (specify)	
Guatemala			

How many years have you lived in the United States? _____

What is your current work status? Please select one. Are you…

- ☐ Working part time
- ☐ Working full time
- ☐ Full- or part-time student
- ☐ Retired
- ☐ Never worked
- ☐ Unemployed/looking for work
- ☐ Receiving disability

What is your average yearly household income (combined income of everyone living in your house)? Please choose the response that fits best.

- ☐ Less than $9,999
- ☐ $10,000-$19,999
- ☐ $20,000-$29,999
- ☐ $30,000-$39,999
- ☐ $40,000-$49,999
- ☐ $50,000-$59,999
- ☐ $60,000-$69,999
- ☐ $70,000-$79,999
- ☐ $80,000-$89,999
- ☐ $90,000-$99,999
- ☐ More than $100,000
- ☐ Prefer not to answer
- ☐ Don't know

What is your current marital status? (Select one)

- ☐ Single
- ☐ Separated
- ☐ Divorced
- ☐ Widowed
- ☐ Married
- ☐ Living with a partner

Do you have a doctor (primary care, family doctor) that you see regularly (routine check-ups, treatment of colds or minor health concerns)? ___ Yes ____ No

Are you currently covered by health insurance? ____ Yes ____ No

If no, skip next question.

What type of health insurance do you have?

_____ Group insurance (through my work or my partner's work)

_____ Government insurance (Medicare, Medicaid)

_____ Military insurance _____ Private insurance

_____ Not applicable; I do not currently have health insurance

Have you ever been denied health insurance for any reason?

_____ Yes

_____ No

If yes, why were you denied insurance?
_____
_____

Is there any other thing that we hadn't asked you that you want to share with us about what impacts our quality of life and your general wellness as a breast cancer survivor or caregiver?

May we contact you in the future for other research studies? You would be free to participate or decline at that time.

_____ Yes, you may contact me about future research

_____ No, I prefer not to be contacted about future research

If Yes: Can you give us other additional telephone numbers or an email address where we can contact you? Please note this information will not be connected with your study data.

_____

To thank you for your time, please indicate which gift card you would like to receive:

☐ Target Stores
☐ Safeway Foods (or other local grocery store)
☐ Amazon.com

NOTE: These stores may change based on feedback from the team.

These are all the questions that we had for you today. Thank you for taking the time to participate in this study. We hope that this will help other survivors and caregivers in the future.
