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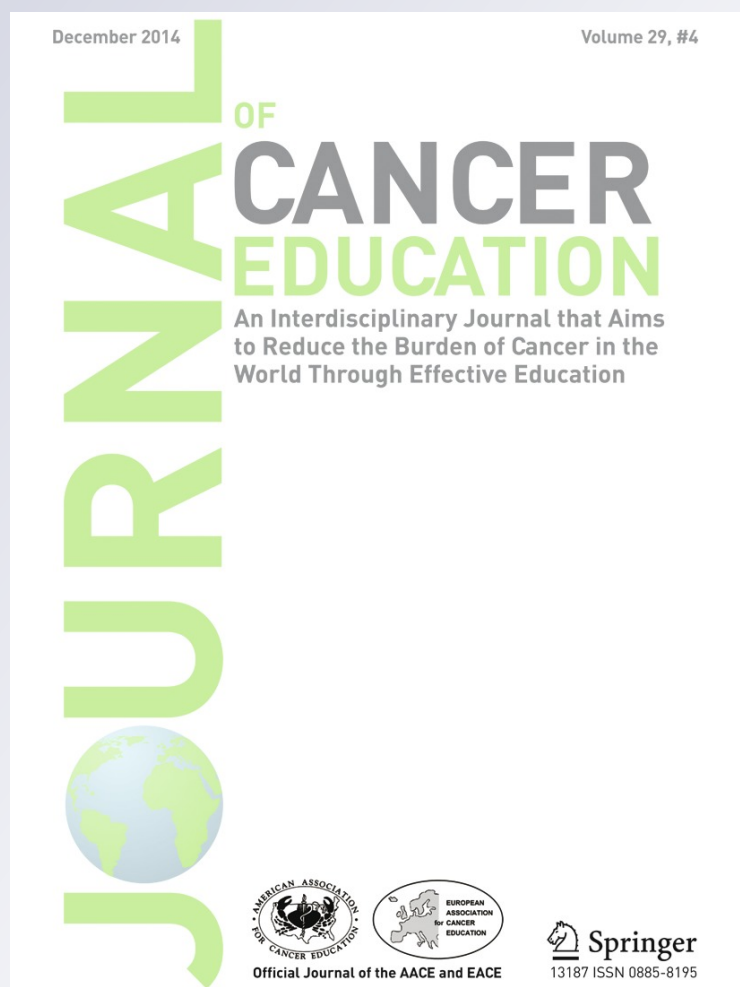
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Educating Low-SES and LEP Survivors About Breast Cancer Research: Pilot Test of the Health Research Engagement Intervention

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Abstract The Health Research Engagement Intervention (HREI) aims to reduce information and access disparities for breast cancer research opportunities among low-socioeconomic status (SES) and limited English proficient (LEP) breast cancer survivors by providing neutral, non-trial-specific information about health research via a trusted patient navigator. Qualitative methods in the context of a community-based participatory research design were used to iteratively design the HREI in collaboration with community-based care navigators from a trusted community organization, Shanti Project, and to locate appropriate research studies in collaboration with a web-based trial-matching service, BreastCancerTrials.org (BCT). Navigators were first trained in clinical trials and health research and then to deliver the HREI, providing feedback that was incorporated into both the HREI design and BCT's interface. Our intervention pilot with low SES and LEP survivors ($n=12$) demonstrated interest in learning about "health research." All 12 participants opted to obtain more information when offered the opportunity. Post-intervention questionnaires showed that three of 11 (27 %) participants independently pursued additional information about research opportunities either online or by phone in the week following the

intervention. Post-intervention navigator questionnaires indicated that navigators could confidently and efficiently deliver the intervention. LEP patients who pursued information independently faced language barriers. The HREI is a promising and potentially scalable intervention to increase access to neutral information about breast cancer research opportunities for low-SES and LEP individuals. However, in order for it to be effective, systems barriers to participation such as language accessibility at sources of health research information must be addressed.

Keywords Health research education · Clinical trial education · Patient navigation · Patient-provider relationship · Health literacy

Introduction

The underrepresentation of minority groups in clinical and behavioral research is a critical issue when considering how to eliminate cancer disparities across the cancer continuum. Diversity of participants in research is necessary to ensure generalizability, as well as the fit and adequacy of treatments and interventions for various subgroups. Despite significant efforts to address the many documented patient, provider, and systems barriers to information about and participation in health research [2–6], minority participation remains a substantial challenge [1, 7–9]. Furthermore, research on participation barriers and recruitment strategies have focused primarily on prevention, screening, and treatment trials [1, 2], with little attention to participation in other types of health research, such as behavioral studies [10] and the patients who have completed active treatment or who are metastatic with stable disease [8]. As a result, critical life-saving treatments and quality of life services developed and validated through research may not address the needs of minority patients.

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The Health Research Engagement Intervention (HREI) was developed to increase access to health research participation opportunities among low-literacy, low-income, low-English-proficient (LEP), and multilingual breast cancer patients and survivors. In the context of community-based participatory research collaboration [11], we examined the potential of community-based patient navigators to educate patients and increase their access to appropriate information about research studies. Patient navigators' potential to reduce barriers to clinical trials participation is a relatively recent area of research. Various models have been explored, yet many of these efforts have focused on recruitment to specific trials [2, 12–16]. In contrast, our study utilized paid staff navigators at a community-based organization, Shanti Project (Shanti), to provide general education about the spectrum of breast cancer research in a neutral manner not tied to enrollment in a specific trial. We also collaborated with BreastCancerTrials.org (BCT), a nonprofit clinical trials matching service, to develop tailored up-to-date information about participation opportunities [17].

Methods

This community-based participatory research study was conducted in three phases: (1) formative research utilizing inductive qualitative methods (reported elsewhere [18]); (2) an iterative intervention development process; and (3) an intervention pilot test (the latter two are described here). Informed consent was obtained from all participants, and the Committee on Human Research at the University of California, San Francisco approved all study protocols.

Study Sites and Population Shanti provides direct services to women in active treatment and through post-treatment wellness activities via trained multilingual navigators who (1) share the language and culture of the lay community (English, Spanish, Cantonese, and Mandarin); (2) provide emotional and practical support to the lay community throughout treatment; (3) participate in health education and wellness activities with patients as they complete treatment and move into survivorship and Shanti's wellness program. Shanti is contractually integrated into the county's department of health's public hospital, serving 450 clients diagnosed with breast cancer annually. Shanti's breast cancer client population is 34 % Asian (primarily Cantonese speakers), 16 % Latino, 19 % White, 12 % African American (the remaining 19 % includes Filipino, Russian, and others); 87 % live at or below 200 % of the poverty level and are severely distressed with income and housing issues. Shanti clients with early stage diagnoses who had completed initial treatments or who were

metastatic with stable disease participated in the development and pilot test of the HREI along with Shanti navigators.

BCT is an online resource dedicated to helping breast cancer patients find clinical trials and other health research opportunities personalized to their situation. Inspired by patient advocates, BCT was initially launched in 2005 as a San Francisco research pilot [17], and then launched nationwide in 2008, listing only studies that have been registered in ClinicalTrials.gov. BCT has attracted primarily highly educated, White users, and thus recognized the need to make substantial changes to communicate with a diverse audience, including LEP and low-literacy breast cancer patients and survivors. BCT partnered with Shanti and UCSF researchers on the present study to enhance the site's ability to share its information with underserved breast cancer patients and survivors and their navigators.

Intervention Development The intervention was developed through a fully collaborative iterative design process. Based on the findings from our formative research and an evaluation of existing materials, we began by designing training materials for navigators and educational materials for clients. Navigators participated as both subjects and researchers in the formative research and were essential at every stage of the iterative design process [18]. Over a period of 5 months, the Navigators participated in two trainings and provided feedback via pre- and post-training questionnaires and post-training individual debrief sessions in the week following the initial training. Each debrief conversation lasted 60 min and included open- and closed-ended questions to assess navigators' comfort with the format of the training and to gather outstanding questions and concerns about the training content and suggestions for the second training.

Intervention Pilot Test For the HREI pilot test, navigators recruited participants from among Shanti's clients during routine phone calls to transition clients from "active care navigation" (intensive treatment support) into the Wellness Program (on-going survivorship support). If clients agreed to participate, navigators scheduled an office appointment to conduct the HREI. Four navigators delivered the intervention to 12 clients over the course of 1 month. Navigators conducted a follow-up telephone survey with both open- and closed-ended questions 1 week after the intervention. Participants received a \$25 gift card and vouchers for transportation to and from the Shanti office in appreciation for their time. In addition, each navigator completed a questionnaire after completing the intervention with two to four clients to obtain data on the following: the length of time spent delivering the intervention, the navigators' perceptions of the participants' attitudes and comfort-level with receiving the intervention, and the navigators' perceptions of delivering the intervention.

Results

Intervention Development

Formative research identified key parameters for the intervention, including the following: (1) provide general information about clinical trials in a simple and neutral manner; (2) use the term “health research” rather than “clinical trials” to include the full range of breast cancer research; (3) maintain consistency with the navigator’s usual role; (4) focus on women who are either out of treatment or metastatic patients with stable disease, i.e., those who are not in crisis and who have established long-term, trusting relationships with their navigator; and (5) address systems barriers with regard to language and literacy³⁵. To develop the intervention, we conducted two 3-hour trainings with navigators (delivered by the research team), to provide them with basic knowledge about health research and collaboratively design the HREI. The first training included (1) a brief history of health research and its relationship to standard treatments; (2) examples of breast cancer research, including post-treatment survivorship, epidemiological, and quality-of-life studies; (3) case studies to illustrate eligibility, enrollment, and participation procedures; (4) a list of questions patients might consider before enrolling in a study; and (5) an introduction to the BCT Navigator Portal and BCT’s health history form. Feedback from the first training as well as formative research was used to design the initial draft of the HREI protocol and to modify BCT.³⁵ In the second training, navigators reviewed the health research basics covered in the first training and the first iteration of the HREI. Navigator feedback during the second training led to the final version of the HREI, which consists of five navigator-delivered components: (1) a simple explanation of health research and its value to the breast cancer community; (2) a “health research resource card” listing resources where patients can obtain information independently; (3) a brief Health History Questionnaire to identify appropriate studies; (4) a tailored list of appropriate research studies from BCT; (5) a review of the listed study descriptions. Throughout, the HREI is characterized by the simple format, neutral approach, and limited scope of information provided.

To address formative research findings of clients’ misunderstanding and mistrust of clinical trials, we developed a simple and neutral clinical trial educational component and used “health research” rather than “clinical trials” throughout the HREI script and on all newly developed print materials. To address navigators’ concerns identified in formative research about delivering clinical trials information beyond their expertise, the scope of the educational component was limited to basic information about health research, and the protocol was detailed in a flow-chart that marked and scripted each component (Fig. 1). A visual aid was developed to help navigators remember key components of the script and to make the

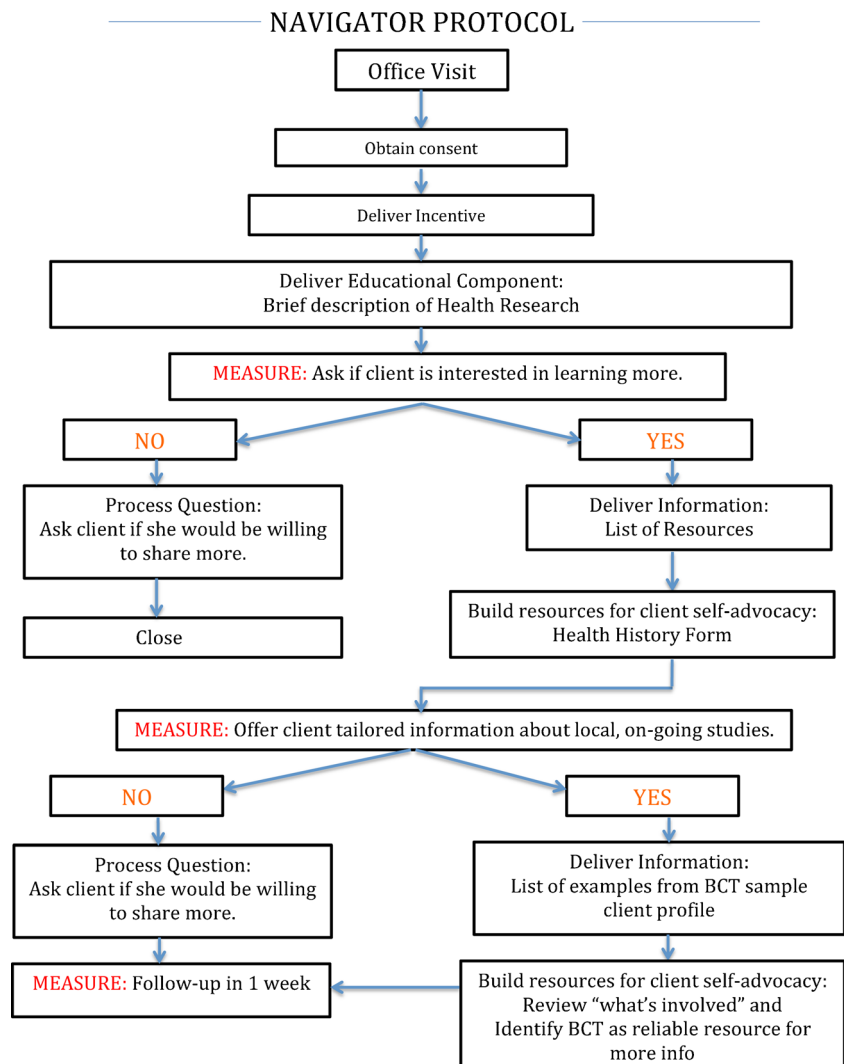
content more accessible to LEP and low-literacy clients as they follow along (Fig. 2). The “health research resource card” enables navigators to direct clients to “health research information experts” at various research access points (including BCT, American Cancer Society, NCI’s Cancer Information Service, and Army of Women) where clients can obtain additional information about available studies (see Fig. 3). The resource cards included both telephone and website addresses and were bilingual English/Spanish and English/Chinese.

The development of the Health History Form and the tailored list of studies that navigators reviewed with clients took into account navigators’ concerns about the relevance and scope of information they provide to patients and other formative data indicating the importance of providing relevant information about studies that are in fact open and accessible. Navigators were also concerned about the accessibility of information portals such as BCT, both for themselves to use with clients and for clients when seeking information independently. For example, navigators would need to know and report their clients’ detailed diagnosis and treatment information, which is beyond the scope usually collected by navigators and beyond most clients’ knowledge about their own health history to complete the Health History Form required to generate “matches” on BCT—trials that match an individual’s eligibility. As a result, we worked with BCT to abbreviate the Health History Form cutting it down to only nine questions needed to identify non-treatment studies open to post-treatment survivors and metastatic patients with stable disease. Navigators reviewed the revised form for literacy level and ease of use. To further increase usability by the navigators, BCT staff created a Shanti page inside the BCT Navigator Portal for “sample client” profiles, representing a range of medical histories among post-treatment survivors and metastatic patients with stable disease like the Shanti clients intervention targets. The BCT team also created a “favorites” tab, which it populated with the studies most relevant for Shanti clients with regard to stage, study type, and location, thereby reducing the interpretation of trial summaries and decision-making required by the navigators about which study information to share with clients, as well as the number of clicks to get to that information.

Intervention Pilot Test

Five navigators carried out the intervention with 12 clients (two navigators each delivered the intervention to two clients in Cantonese; two navigators delivered the intervention to one and three clients in English; and one navigator delivered the intervention to four clients in Spanish). Twelve out of 14 clients who were invited to participate by their navigator during the usual “transition to Wellness Program telephone call” agreed to participate. Navigators administered a follow-up questionnaire, including closed- and open-ended questions, by phone 1 week after the intervention to measure health research information

Fig. 1 Navigator protocol flowchart



seeking behavior and to obtain qualitative data on the intervention's effects. Eleven of the 12 participants (92 %) were reached



Fig. 2 Visual aid of the key components

for the follow-up questionnaire. Three of 11 (27 %) had pursued information about health research information using the Health Research Resource Card in the week after the HREI, including one Spanish- and two Chinese-speakers, all of whom faced language barriers at the sites they called (ACS and BCT). An additional three out of 11 (27 %) reported that they had been busy that week but still intended to call one of the numbers on the Resource Card.

In the post-intervention questionnaire, nine out of 11 participants (82 %) reported that they were interested in learning more about health research, offering that they hoped to learn about new treatments or to help others. In response to the question, “How would you like to learn more about health research or other studies?” Spanish-speaking participants indicated that they would prefer to receive information about studies in-person with visual aids or by phone, rather than from the computer. All participants said that they felt comfortable with their navigator providing this new information. In response to the question “How did you feel about me, as

Fig. 3 Health research and website information card

your navigator, raising this topic?” One noted that she felt more comfortable hearing this information from her navigator than she would have from “other professionals.” Others indicated that the protocol was consistent with the navigators’ role and their own breast cancer journey: “It felt like a sensible step to take where I am in my breast cancer journey – post-treatment – to talk about health research and studies to participate in.” Another said, “The health research piece fits the script of a navigator, and I did think it was appropriate now that I am done with my surgery and radiation.”

Findings from the navigators’ questionnaire or “reflection form” completed after delivering the intervention with at least two clients of the intervention found that it took an average of 25 min to deliver, and thus was consistent with routine resource information delivery and not burdensome. The reflections showed that navigators’ confidence in delivering the intervention grew with practice, and that they perceived the protocol to be clear, feasible, and effective in engaging clients. Navigators also reported that they felt confident that the intervention did not negatively impact or disrupt the navigator-client relationship. They found the visual aid particularly useful, as a mnemonic device for key components of the script; as a tool to engage LEP or low-literacy clients; and as a locative alternative to direct eye contact for clients who are less comfortable with direct eye contact due to cultural norms or personal preferences.

Discussion and Conclusions

The goal of this study was to develop facilitated access to health research participation opportunities through a source trusted by low-income, LEP women. To do so, we developed

and pilot tested a navigator-delivered intervention to increase the access of underserved breast cancer patients and survivors to information about health research in a manner appropriate to their language, literacy, and culture. The collaborative and iterative development process reflects the CBPR approach; community-based navigators were critical at each stage in the development and implementation process. The navigators’ knowledge of the patient population as trusted providers and peers, and their training in a non-directive, client-centered mode of communication (the Shanti Model of Peer Support™), made them crucial partners in the development process and ideally suited to deliver the intervention.

In contrast to some studies that have explored the role of navigators and other lay health workers in relation to health research [16, 19–22], our intervention provided neutral information rather than education for recruitment to a specific trial. Furthermore, the HREI is tailored for low-income, LEP, post-treatment breast cancer survivors and metastatic patients with stable disease. By engaging women who were not in the crisis of an initial diagnosis, we aimed to identify women who might be more receptive to receiving additional information related to their health status, without the urgency that accompanies being recruited to participate in a treatment trial at the time of diagnosis. The goal was thus to expose the women to a range of research participation opportunities they might be eligible for at present (such as behavioral, epidemiological, genetic studies), while also laying the ground for a conversation about a treatment trial if they have a recurrence or need treatment for their metastatic disease later on. As such, our approach has the potential to create an educated population of potential research participants who are familiar with health research and have neutral or positive attitudes toward it.

The pilot test of this intervention successfully engaged low-income and LEP patients' interest in health research. The participants showed an interest in learning about health research from their navigators, and a quarter sought additional information on their own in the week after the intervention. While the number of participants in the pilot makes it inappropriate to extrapolate, this study demonstrates the potential to engage and empower low-income and LEP breast cancer patients and survivors to seek health research information independently if introduced to it by a trusted source and provided appropriate access points. The fact that two of the three participants who sought information on their own faced language barriers at sites providing information about health research studies further reinforces the need to address systemic barriers to access, including at the access points themselves [23–25]. Although we had addressed some systems issues to make BCT more user friendly for navigators and clients and to facilitate the navigators' quick and easy access to relevant information for their clients, additional improvements are needed to address both language and literacy barriers at BCT (and other sources of health research information). Some changes, such as making study descriptions more accessible and appropriate for low-literacy readers and establishing a multilingual information line to enable non-English speakers to obtain additional information about studies by telephone are underway.

Despite the small sample size and that participants were drawn from one city and the navigators from one community-based organization, the HREI pilot produced promising results that we plan to test in a larger randomized controlled trial for effectiveness. In addition, the development process and pilot study produced valuable changes to the organizations involved and identified additional changes needed at health research information access points such as BCT, ACS, and NCI that if implemented, will help to make these organizations' information about research studies more accessible to low-literacy and LEP women who have had breast cancer. Significantly, this approach has the potential to build individual and community access to information and self-sufficiency in obtaining the information in an ongoing manner. In the long term, this community knowledge and access could help to increase not only access to information about research opportunities but also participation of underserved patients and survivors in breast cancer research.

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