Telehealth intervention for Latina breast cancer survivors: A pilot

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Abstract
Aim: This study was a pilot test of the Latina Breast Cancer Survivorship Intervention, a survivorship self-management intervention delivered via telephone.

Materials and methods: This study used a wait-list control design with random assignment to either (1) support and early education or (2) support and delayed education. Latina breast cancer survivors were recruited through the Florida Cancer Data System Registry. Latinas with stage I–III breast cancer who completed primary cancer treatment 3 years prior to study enrollment were eligible. The Latina Breast Cancer Survivorship Intervention consisted of three education sessions delivered weekly via telephone and six telephone support calls, both delivered by a native Spanish speaker. Primary outcome variables included physical well-being, emotional well-being, fatigue, pain, and depressive symptoms. Data collection occurred at baseline, 3 months, and 6 months.

Results: In total, 40 Latina breast cancer survivors who were middle-aged to older, married, with health insurance, and Spanish as preferred language enrolled in the Latina Breast Cancer Survivorship Intervention. Data were analyzed using mean change scores. Overall, physical and emotional well-being remained similar over time with well-being scores poorer compared with the general population. Pain levels improved over 6 months and showed a high effect size. Fatigue scores improved at 3 months and showed a moderate effect size. Depressive symptoms remained elevated but were not clinically significant.

Conclusion: Telephone-based Latina Breast Cancer Survivorship Intervention reached Latina breast cancer survivors for survivorship education and support. Self-management of pain and fatigue showed improvement over time.

Keywords
Latina breast cancer survivors, mental well-being, physical well-being, quality of life, self-management, survivorship intervention, telehealth

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Introduction
Breast cancer is the most prevalent cancer among Latina women in the United States with an estimated 19,800 diagnosed annually.1 Nearly 162,000 Latina breast cancer survivors (BCS) live in the United States, and the numbers of survivors are expected to rise with the increase in the Latino population.2 The good news is the improved long-term survival among Latina BCS with current data indicating 88% five-year survival.2 However, Latinas continue to experience disparities across the cancer continuum from access to screening and diagnosis, cancer treatment, and survivorship care.3 A large gap occurs during survivorship where there are few linguistic and culturally based interventions

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to ameliorate problems and improve quality of life for Latinas. 3–5

Recently, Badger and colleagues 6 reported on the use of telephone-delivered health education and interpersonal counseling to improve quality of life among Latina BCS and their support partners.

The authors adapted an evidence-based survivorship program, the Breast Cancer Education Intervention (BCEi)7 specifically for Latina BCS, and delivered the program via telephone. 8 First, the authors translated the BCEi print materials into Spanish using a certified translator. 9 Second, the authors based the translated materials using broadcast Spanish, a type of language that could be idiomatically understood by a wide variety of Spanish speakers throughout Mexico, Puerto Rico, and Latin America. 10 Broadcast Spanish was particularly relevant because of the diversity of the target population of Latina BCS living in Florida. 11 Third, the authors wrote all education and support materials at the sixth-grade reading level consistent with the original BCEi. 7,12 Fourth, the authors evaluated the print materials for cultural relevance using cognitive interview. 8 In doing so, they uncovered meaningful cultural concepts of familismo (i.e. central focus on family values), marianismo (i.e. taking care of others first before self), and personalismo (i.e. interpersonal warmth between provider and patient). 5,13,14

A detailed discussion of the process of translation, cognitive interview, cultural adaptation, and readability of the Latina Breast Cancer Survivorship Intervention (LBCSI) is reported elsewhere. 8 Feasibility based on both acceptability and high satisfaction with the LBCSI was also previously described. 8 Here, the authors describe the pilot results of the LBCSI, specifically the changes in physical and mental well-being 3 and 6 months after receipt of LBCSI education.

Materials and methods

Prior to study initiation, human subjects’ approval was obtained from the Florida Department of Health (DOH) Institutional Review Board, the Cancer Registry of the Florida Cancer Data System (FCDS), and the University of Alabama at Birmingham.

The LBCSI pilot study was part of a large parent breast cancer survivorship intervention study that was conducted in the State of Florida. 15 Recruitment procedures of the parent study took place via the FCDS Registry, a population-based cancer program. 16 The LBCSI recruitment mirrored the parent study. The investigators used the database to identify women with Spanish surnames, last known address, and telephone number.

Eligibility criteria for the LBCSI included Latina BCS with Stage 0–III breast cancer, within the first 3 years of completing primary breast cancer treatment, age 21 years and older, with telephone or cell phone access, and living in Florida. Exclusion criterion was metastatic disease at diagnosis. Initial contact with the LBCSI invitation and response forms in both English and Spanish was through the mail. Latina BCS expressing interest in the study received follow-up contact from a bilingual research staff. Records of those who did not respond or declined were deleted from the recruitment database to prevent recontact. Figure 1 shows the CONSORT. Of the 93 Latinas who responded with interest, a total of 40 (43%) Latina BCS enrolled.

LBCSI

Participants were randomly assigned to either the Support and Early Education (EE) Intervention (n = 21) or the Support and Delayed Education (DE) Intervention (n = 19) group. The difference between the two groups was in the timing of the education with one group receiving education sessions in the first month and the second group receiving education sessions in the sixth month of participation. The LBCSI occurred via telephone and generally took about 45–60 min. 8 The individual support and education sessions were conducted in the participants’ preferred language, the majority of whom chose Spanish.

The education sessions addressed common concerns among BCS and emphasized self-management techniques. 7,8 The first education session addressed physical complaints related to fatigue (e.g. sleep disturbances, changes in sleep patterns, nutrition, and energy conservation), pain (both related to primary treatment and adjuvant therapy), and lymphedema. The second education session focused on physical changes such as menopausal
complaints (e.g. hot flashes, sleep problems, sexuality, and fertility), ways to maintain a healthy lifestyle (e.g. nutrition, physical activity, cancer and routine health surveillance and maintenance), and the financial impact of breast cancer. The third education session addressed the emotional and spiritual impact of breast cancer diagnosis and treatment, including anxiety, fear of recurrence, meaning in illness, and the social and family impact of breast cancer. The LBCSI written education and self-management materials, described above, supplemented the education sessions.

Six telephone support calls further helped to reinforce self-management of health and understanding of side effects. Participants received clarification about their survivorship care and self-management during the telephone support calls. Figure 2 is a schematic presentation of the intervention components.

The interventionists were bilingual, native Spanish speakers. They received training in breast cancer survivorship, principles of survivorship self-management, and understanding of core Latino values. Education sessions were tape-recorded for the purpose of evaluating intervention fidelity. Concerns about fidelity drift were discussed at monthly research team meetings.

Data collection

Participants completed two self-report measures at baseline prior to intervention, and at 3 and 6 months after completing the education sessions. They received paper copies of the self-report measures via mail and provided answers via the telephone to an LBCSI research staff.

- **Demographic and cancer treatment characteristics** were collected using the 32-item Breast Cancer Survivor Sociodemographic and Treatment Survey used in prior studies by the investigators and were collected at baseline only.
- **Physical well-being and emotional well-being data** were collected using the Medical Outcomes Survey Short-Form 36 Health Survey (SF-36). The SF-36 is a 36-item questionnaire that measures quality of life across eight domains (i.e. physical functioning, role limitations due to physical health, role limitations due to emotional problems, fatigue, emotional well-being, social functioning, pain, and general health). The eight domains are often aggregated into two summary measures of physical and mental well-being: the Physical Component Score (PCS) and Mental Component Score (MCS). Scores range from 0 to 100, with higher scores indicating better quality of life. A norm score of 50 is indicative of a level comparable to that of the average adult in the U.S. population.
- **Depressive symptoms** were measured using the Center for Epidemiologic Studies Depression Scale (CES-D), a widely used short self-report scale designed to measure depressive symptoms in the general population. The total score ranges from 0 to 60, where higher scores indicate increased depressive symptomatology. Scores ≥ 16 suggest clinically significant levels of psychological distress and warrant referral to a mental health professional.
Statistical analysis

Demographic data were summarized using frequencies and percentages. The mean and standard deviation were reported for outcome measures. All participants received the LBCSI support calls and education sessions, and were evaluated 3 and 6 months after completing the education sessions. Thus, data from both groups were combined into one group for analysis. The authors report data at baseline, 3, and 6 months after completing the education sessions. The mean differences at 3 months compared with 6 months after education were analyzed using mean change scores. Since this was a pilot study, p values from the analysis are not reported and the study does not involve any statistical inferences/hypothesis testing. Rather, the effect sizes of the difference in means, a key element in pilot studies, are reported.\(^{20}\) The mean change in scores was quantified using the Cohen's d effect sizes and the size of the effect was classified as low (.20), moderate (.50), and high (.80).\(^{21}\) Statistical analyses were performed using R software\(^{22}\) and used the \texttt{lslr}\(^{23}\) package for calculating the effect size statistics.

Results

Sample characteristics

A total of 40 Latinas enrolled in the LBCSI (see Figure 3). Sociodemographic and treatment characteristics are summarized in Table 1. Participants were from a diversity of Spanish-speaking countries, including Cuba, Colombia, Costa Rica, Honduras, Venezuela, Guatemala, Argentina, Panama, Peru, the Dominican Republic, and Mexico, in addition to Puerto Rico. Overall, the sample was middle-aged, married, had health insurance, and preferred Spanish as their predominant language. While the participants were well educated, 40% reported a family income of US$20,000 or less per year.

Participants received standard breast cancer treatment with a combination of surgery, radiation therapy, chemotherapy, and/or hormonal therapy. The majority received primary treatment with lumpectomy (68%) and radiation therapy (80%), followed by mastectomy (45%). Seventy-three percent received chemotherapy, and 58% received endocrine therapy. This sample was relatively new to cancer survivorship with a mean survivorship of 2 years (range=0–3 years). The majority reported not having access to psychosocial support.

Complete data for the study measures were available for 25 (16 EE+9 DE) at baseline prior to education sessions, 12 (7 EE+5 DE) 3 months after education, and 16 (11 EE+5 DE) 6 months after education. All missing data were excluded from the analysis.

Physical well-being

Overall, participants reported lower aggregate PCS scores (mean=46.02) when compared with the general population (mean=50). There was little change noted in PCS scores from baseline scores before the education sessions to 3 and 6 months after completion of education sessions. Similarly, physical functioning and role limitation scores reflected PCS scores with a low mean score (45.73 and 46.62, respectively) which improved slightly 6 months later (46.02 and 47.84, respectively). Mean pain scores showed improvement with a high effect size from baseline scores to 3 months (43.02 vs 52.08, d=0.87) and 6 months later (43.02 vs 47.31, d=.36). Table 2 lists the physical well-being, emotional well-being, and depressive symptom scores.

Emotional well-being

Overall emotional well-being using the MCS improved slightly at 3 months compared with baseline (48.77 vs 50.29) and dropped slightly 6 months later (49.36). The MCS scores were similar to the general population.

The trend for fatigue/energy showed improvement. Scores changed in a positive direction after education sessions to 3 months later and having a moderate effect size (48.30 vs 51.81, d=0.38). Fatigue increased slightly (50.83) 6 months later and showed a moderate effect size (48.30 vs 50.83, d=0.27).

Depressive symptom scores reported with the CES-D worsened slightly from baseline to 3 months (13.68 vs 14.75, d=0.08). The overall observed effect size for the mean differences was small. Reported depressive symptom scores were not at the threshold (>16) to recommend clinical referral and evaluation.

Discussion

Telephone-delivered LBCSI reached Latina BCS for self-management during survivorship. This pilot study described associated changes in physical and mental well-being after LBCSI support and education.

Overall physical well-being scores were slightly poorer compared with the general population. However, these scores were similar compared with non-Latina BCS.\(^{24}\) Our
baseline pain findings among Latina BCS were similar to two recent studies. The first, reported by Lee et al., evaluated pain after cancer treatment among Hispanic and Caucasian BCS. The investigators found that Hispanic BCS reported significantly higher pre- and post-radiation therapy pain compared with Caucasian BCS. The second, reported by Eversley et al. in a study of post-treatment symptoms among 116 BCS, of whom 29 (25%) were Latina, found increase in pain, fatigue, and depression among Latinas compared with other minorities.

In the LBCSI, Latinas reported improvement in pain at both 3 and 6 months. During the LBCSI support and education sessions, the interventionists described pain as a very common side effect in survivorship. They supported Latina BCS to share their pain experiences, allowed them to speak openly and freely about pain, and offered self-management strategies to identify pain and differentiate common from uncommon pain symptoms.

Fatigue improved 3 months after the LBCSI but returned to baseline fatigue levels 6 months later. Similar to pain symptoms noted above, participants did not consider fatigue as a topic for open discussion, rather for quiet silence. Participants learned for the first time that fatigue was a real and common and lingering side effect after treatment. During the telephone support and education sessions with each participant, interventionists used active listening and personalismo to help them talk about how fatigue affected them and helped to develop self-management strategies to identify pain and differentiate common from uncommon pain symptoms.

Depressive symptoms increased at 6 months. However, the average depressive symptom risk score was 13 and is considered in the moderate range that did not reach the clinical threshold of 16 considered for prompt referral. Nevertheless, the report of depressive symptoms was an
improvement because this symptom, similar to pain and fatigue, is generally underreported. Christie and colleagues examined depressive symptoms, sexual function, and body image in 677 low-income BCS, of whom 425 were Hispanic (63%). They found that 38% (n = 162) of Hispanic women scored above the cut score for depressive symptoms more than a year after diagnosis.

Findings showed that self-management interventions can be delivered via telephone to Latina BCS. The findings of this pilot study support conclusions of Badger and colleagues who showed that telephone-based interventions were both feasible and acceptable for Latina BCS.

Limitations and strengths

Several limitations are noted. First, population-based recruitment was dictated by the parent study and is considered a limitation. Of the 92 Latina BCS who responded expressing interest in the study, 40 (42%) enrolled. Second, time for follow-up data collection at 3 and 6 months may have been burdensome. Of the 40 who enrolled, complete data were available for 25 (63%) immediately after the LBCSI intervention, 12 (30%) at 3 months, and 16 (40%) at 6 months. Third, fatigue scores at 6 months were similar to scores reported before the LBCSI. Thus, while the intervention addressed fatigue, there was little change in fatigue scores over time.

Likewise, the LBCSI had several strengths. First, pilot findings indicate that the LBCSI is a promising intervention to mitigate pain and fatigue during survivorship for Latina BCS. Second, there are very few reported studies of symptoms experienced specifically by Latina BCS. In general, Latinas or Hispanic women are considered as part of multi-ethnic descriptive studies. Third, the LBCSI pilot study incorporated culturally tailored interventions based on cognitive interviews recommended by and for Latina BCS. Fourth, delivery of the LBCSI in the preferred language of the participants was a strength. In a related study, Banas et al. also found that participants preferred Spanish language interventions delivered by Spanish speakers. And finally, our findings contribute to the few available validated comprehensive survivorship interventions that are adapted and designed for Latinas.

Conclusion

The LBCSI pilot study using telephone to reach Latina BCS for survivorship education and support may be of benefit. Self-management of pain and fatigue showed improvement over time.

Summary points

- This was a pilot study of the LBCSI, a survivorship self-management intervention delivered via telephone.
- The LBCSI consisted of three education sessions delivered weekly via telephone and six telephone support calls, both delivered by a native Spanish speaker.
- The LBCSI was one of the few studies that included only Latinas in the sample.
- Overall, physical and emotional well-being remained similar over time with well-being scores poorer compared with the general population.

| Variable                  | After education | Comparison with baseline |       |       |       |       |
|---------------------------|----------------|--------------------------|-------|-------|-------|-------|
|                           | (N = 25)       |                          | 3 months from education | 6 months from education |       |       |
|                           | Mean          | SD           | Mean          | SD | d        | Mean          | SD | d        |
| SF-36 PCS                 | 46.02         | 11.33        | 46.85         | 10.39 | 0.08    | 47.1          | 10.2 | 0.1     |
| Physical functioning       | 45.73         | 10.52        | 43.16         | 11.5 | 0.24    | 46.02         | 9.3  | 0.03    |
| Role limitations (physical)| 46.62         | 12.06        | 46.22         | 12.96 | 0.03    | 47.84         | 11.02 | 0.1     |
| Pain                      | 43.02         | 11.47        | 52.08         | 7.82  | 0.28    | 47.31         | 12.71 | 0.36    |
| General health             | 50.36         | 10.55        | 48.16         | 10.57 | 0.21    | 48.14         | 11.37 | 0.2     |
| SF-36 MCS                 | 48.77         | 10.49        | 50.29         | 10.55 | 0.14    | 49.36         | 10.82 | 0.06    |
| Emotional well-being       | 49.53         | 8.85         | 50.82         | 9.08  | 0.14    | 47.89         | 11.43 | 0.17    |
| Role limitations (emotional)| 44.38         | 14.42        | 44.81         | 15.56 | 0.03    | 48.1          | 12.59 | 0.27    |
| Social functioning         | 49.1          | 9.15         | 49.45         | 9.94  | 0.04    | 48.32         | 9.27  | 0.09    |
| Energy/fatigue             | 48.3          | 8.85         | 51.81         | 10.18 | 0.38    | 50.83         | 10.35 | 0.27    |
| CES-D                     | 13.68         | 13.59        | 14.75         | 15.06 | 0.08    | 13.81         | 12.24 | 0.01    |

SD: standard deviation; SF-36: Short-Form 36 Health Survey; PCS: Physical Composite Score; MCS: Mental Composite Score; CES-D: Center for Epidemiologic Studies Depression Scale.

aAfter Education (25) = Early (16) + Delayed (9).
b3 months from Education (12) = Early (7) + Delayed (5).
c6 months from Education (16) = Early (11) + Delayed (5).
dEffect size, Cohen’s d using pooled SD at baseline.
- Pain levels improved over 6 months and showed a high effect size.
- Fatigue scores improved at 3 months and showed a moderate effect size.
- Depressive symptoms remained elevated but were not clinically significant.
- The LBCSI can be used as the basis for a larger clinical trial of Latina BCS.

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Declaration of conflicting interests

The Florida Cancer Incidence Data used in this report were collected by the Florida Cancer Data System under contract with the Department of Health. The views expressed herein are solely those of the authors and do not necessarily reflect those of the Florida Department of Health.

Ethical conduct

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human and animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

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