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Nuevo Amanecer: Results of a Randomized Controlled Trial of a Community-Based, Peer-Delivered Stress Management Intervention to Improve Quality of Life in Latinas With Breast Cancer

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Latinas are the fastest growing US racial/ethnic group. With a population growth rate 4 times that of the total US population (24.3% vs 6.1%), they accounted for half of the nation's growth between 2000 and 2006.¹ Breast cancer is the most frequently occurring cancer and leading cause of cancer death among Latinas.² Latinas experience worse breast-cancer-recurrence-free survival than White women.³ Latinas are at higher risk for psychosocial and physical sequelae of breast cancer than White women and report higher rates of anxiety, depression, fear of recurrence, fatigue, and pain and worse health-related quality of life (HRQOL).^{4–9} Limited English proficiency, employment, and insurance coverage; lack of transportation; and problems paying for treatment increase their risk of distress.⁶ Anxiety among Spanish-speaking patients is common because they often do not understand the diagnosis or treatment and are less involved in patient-centered decision-making.¹⁰

These factors can chronically elevate stress levels among Latinas after breast cancer. In fact, disparities in HRQOL between Latinas and non-Latinas with breast cancer have been partially explained by higher stress levels.⁵ Higher levels of chronic stress and fatigue can cause hypothalamic–pituitary–adrenal axis dysregulation and inflammatory responses.^{3,11,12}

Among breast cancer survivors, stress management interventions improve HRQOL, including increased positive affect and lifestyle changes; decreased anxiety, stress, emotional distress, and thought intrusion^{13–18}; and improved sleep quality.^{14,19} These interventions may also produce beneficial changes in biomarkers of the hypothalamic–pituitary–adrenal axis¹⁴ and immune functioning.¹⁸ However,

such studies are lacking among Latinas with breast cancer. Translation of evidence-based stress management interventions could help address this gap and reduce ethnic disparities in psychosocial health of Latinas with breast cancer.

We present results of a randomized controlled trial of a peer-delivered cognitive–behavioral stress management (CBSM) program called *Nuevo Amanecer* (“a new dawn”) for Spanish-speaking Latinas with breast cancer. The program was developed using community-based participatory research methods for translating evidence-based interventions for underserved populations²⁰ through a collaboration between the University of California, San Francisco; *Círculo de Vida*

Objectives. We evaluated a community-based, translational stress management program to improve health-related quality of life in Spanish-speaking Latinas with breast cancer.

Methods. We adapted a cognitive–behavioral stress management program integrating evidence-based and community best practices to address the needs of Latinas with breast cancer. Spanish-speaking Latinas with breast cancer were randomly assigned to an intervention or usual-care control group. Trained peers delivered the 8-week intervention between February 2011 and February 2014. Primary outcomes were breast cancer–specific quality of life and distress, and general symptoms of distress.

Results. Of 151 participants, 95% were retained at 6 months (between May 2011 and May 2014). Improvements in quality of life from baseline to 6 months were greater for the intervention than the control group on physical well-being, emotional well-being, breast cancer concerns, and overall quality of life. Decreases from baseline to 6 months were greater for the intervention group on depression and somatization.

Conclusions. Results suggest that translation of evidence-based programs can reduce psychosocial health disparities in Latinas with breast cancer. Integration of this program into community-based organizations enhances its dissemination potential. (*Am J Public Health.* 2015;105:e55–e63. doi:10.2105/AJPH.2015.302598)

Cancer Support and Resource Center; and a coalition of community-based organizations and clinical partners.^{21,22}

METHODS

In this 6-month randomized controlled trial, we compared the *Nuevo Amanecer* intervention with a usual-care control group (control group participants were offered the program after the trial). We examined the program's effectiveness in improving several dimensions of HRQOL and distress at 3 months and 6 months. We selected the 3-month interval because benefits from these types of interventions in women with breast cancer have been demonstrated after 6 to 12 weeks.^{23–25}

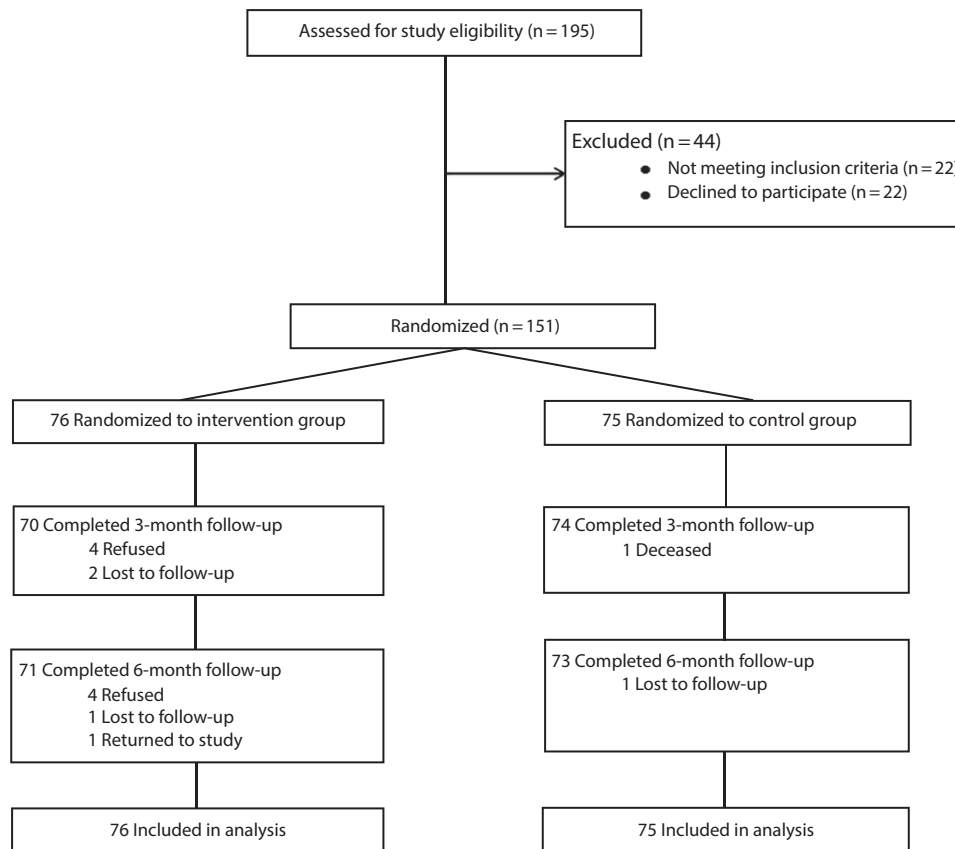


FIGURE 1—Flow of participants from screening to completion of final follow-up assessment: *Nuevo Amanecer* study; San Francisco Bay Area, CA; February 2011–May 2014.

Participants

The study population consisted of Spanish-speaking Latinas with breast cancer residing in 5 Northern California counties. Inclusion criteria were (1) 1 year or less since diagnosis with stage 0 to stage IIIC primary breast cancer; (2) living in Alameda, Contra Costa, San Francisco, San Mateo, or Santa Clara County; (3) primarily Spanish speaking or Spanish monolingual; and (4) self-identifying as Latina. Exclusion criteria were (1) previous cancer diagnosis except for nonmelanoma skin cancer, (2) terminal illness, or (3) stage IV breast cancer (distant metastasis). We excluded women with metastatic cancer because their survival rates decline dramatically compared with those of women diagnosed at earlier stages, suggesting that their psychosocial concerns differ (greater emphasis on symptomatic relief, existential matters).²⁶ Recruitment was conducted by trained

bilingual Latinas employed by the community-based organization partners on the project.²¹

Nuevo Amanecer Intervention

The *Nuevo Amanecer* program and its development are described in detail elsewhere.^{21,22} Program development emphasized appropriate methods for translating evidence-based interventions for underserved populations²⁰ to address known determinants of HRQOL disparities in Latinas with breast cancer. *Nuevo Amanecer* integrates an evidence-based CBSM program,²³ a community best-practices intervention offered at *Círculo de Vida* for Latinas, literature, and formative research. Our formative work identified several unique needs of Latinas with breast cancer (e.g., the intervention needs to address lack of comprehensible cancer information, feelings of powerlessness and fear of death) and optimal

delivery mechanisms (e.g., culturally competent peer support).²²

Adaptations to address known determinants and Latinas' needs included translation into low-literacy (sixth-grade-level) Spanish with images, integration of culturally appropriate content, delivery by trained Latina breast cancer survivors rather than professionals, emotional support, and simple information on cancer and its treatment. Adaptations were guided by our community advisory board, *Círculo de Vida* staff, and the author of the evidence-based program.

Social-cognitive theory served as the conceptual framework for the intervention.²⁷ The program emphasized cognitive-behavioral coping skills training, coaching, and modeling to actively manage stress and emotions. Because vulnerable populations typically reside in high-stress environments and perceive

TABLE 1—Baseline Characteristics of Spanish-Speaking Latina Participants With Breast Cancer: *Nuevo Amanecer* Study; San Francisco Bay Area, CA; February 2011–May 2014

Characteristics	Intervention Group (n = 76), Mean ±SD or No. (%)	Control Group (n = 75), Mean ±SD or No. (%)	P ^a	Total Sample (n = 151), Mean ±SD or No. (%)
Age, y	50.8 ±11.9	50.2 ±9.9	.76	50.5 ±10.9
Acculturation (scale 1–5) ^b	1.4 ±0.6	1.3 ±0.5	.31	1.3 ±0.6
Educational attainment				
< sixth grade	50 (66)	50 (67)	.78	100 (66)
Sixth grade to < high school	15 (20)	12 (16)		27 (18)
High school graduate	11 (14)	13 (17)		24 (16)
Health insurance ^c				
Any private	11 (14)	10 (15)	.95	21 (15)
Public insurance only	62 (82)	56 (82)		118 (82)
None	3 (4)	2 (3)		5 (3)
Employed full or part time	12 (16)	14 (19)	.64	26 (17)
Any financial hardship in past y	59 (79)	56 (77)	.78	115 (78)
Ethnicity				
Mexican	50 (66)	52 (69)	.6	102 (68)
Central American	20 (26)	15 (20)		35 (23)
South American	6 (8)	8 (11)		14 (9)
Married or living with a partner	35 (46)	45 (60)	.09	80 (53)
Poor or fair self-rated health	51 (67)	45 (62)	.49	96 (64)
Presence of chronic medical condition	37 (49)	40 (53)	.57	77 (51)
Clinical and treatment characteristics				
Type of breast cancer				
DCIS	20 (26)	20 (27)	.96	40 (26)
Invasive	56 (74)	55 (73)		111 (74)
Stage				
0	20 (26)	20 (27)	.73	40 (26)
1	12 (16)	11 (15)		23 (15)
2	31 (41)	26 (35)		57 (38)
3	13 (17)	18 (24)		31 (21)
Surgery				
Breast conserving	43 (57)	41 (55)	.81	84 (56)
Mastectomy	33 (43)	34 (45)		67 (44)
Adjuvant treatment				
Both chemotherapy and radiation	33 (43)	27 (36)	.58	60 (40)
Only radiation	18 (24)	24 (32)		42 (28)
Only chemotherapy	14 (18)	11 (15)		25 (17)
No treatment	11 (15)	13 (17)		24 (16)
Breast cancer-specific quality of life^d				
Physical well-being (scale 0–24)	15.29 ±5.78	16.76 ±5.02	.1	16.0 ±5.5
Social/family well-being (scale 0–20)	13.67 ±4.42	12.66 ±4.25	.15	13.2 ±4.4
Emotional well-being (scale 0–20)	12.07 ±4.91	12.86 ±5.14	.33	12.5 ±5.0
Breast cancer concerns (scale 0–28)	16.52 ±5.43	17.33 ±5.08	.34	16.9 ±5.3
Enjoyment of life (scale 0–16)	8.92 ±3.80	9.22 ±3.43	.61	9.1 ±3.6

Continued

a limited sense of control, acquisition of stress management skills constitutes a critical, practical intervention to enhance their abilities to cope with stressful situations. Thus, program components aimed to increase self-efficacy for cancer coping, use of coping skills, and perceived social support, which could improve HRQOL and reduce distress. Eight weekly modules covered managing the initial impact of cancer, finding cancer information, getting support, identifying helpful and unhelpful thoughts, managing thoughts and mood, stress management techniques, managing activities that affect mood, and goal setting.²¹ Modules addressed 3 social-cognitive theory components: self-efficacy (e.g., accessing information, managing thoughts and activities affecting mood), outcome expectations (e.g., recognizing and restructuring unhelpful thoughts about cancer and the future), and self-regulation (e.g., self-monitoring and adapting behaviors and cognitions until goals were met).

The program was delivered by trained *compañeras* (companions). *Compañeras* were bilingual or Spanish-monolingual Latina breast cancer survivors who had completed active treatment and were at least 3 years postdiagnosis with no recurrence. *Compañeras* participated in 3 consecutive 8-hour training sessions conducted by academic and community partners.²¹ The *Nuevo Amanecer* program was delivered face to face in participants' homes for 8 weeks. Each week, one 90-minute module was presented using visuals and hands-on exercises to teach and reinforce concepts and skills. Control group participants received usual care until after the 6-month assessment, at which time they were offered the intervention.

Data Collection

Baseline, 3-month, and 6-month assessments corresponded with our aims of evaluating the 8-week intervention soon after completion and retention of benefits after program termination. Recruiters conducted 60-minute baseline assessments in person.

An experienced, bilingual research associate blinded to participants' group assignment conducted the 3- and 6-month 30-minute telephone surveys. Data were collected and managed using a secure Web-based tool, Research Electronic Data Capture (Harvard Catalyst, Boston, MA).²⁸ Participants were compensated

TABLE 1—Continued

Overall quality of life (scale 0–108)	66.46 ± 16.92	68.83 ± 15.33	.37	67.6 ± 16.1
General symptoms of distress^e				
Anxiety (scale 0–4)	0.93 ± 0.84	1.01 ± 0.88	.58	0.97 ± 0.86
Depression (scale 0–4)	0.93 ± 0.84	0.75 ± 0.76	.16	0.84 ± 0.80
Somatization (scale 0–4)	0.93 ± 0.78	0.75 ± 0.59	.1	0.84 ± 0.70
Breast cancer-specific distress^f				
Intrusive thoughts scale (scale 0–35)	7.96 ± 8.46	8.65 ± 8.91	.63	8.30 ± 8.66

Note. DCIS = ductal carcinoma in situ.

^aCompares differences between intervention and control group at baseline.

^bMarin language scale; higher score indicates greater acculturation to English.

^cTotals do not add up because of missing data (n = 7).

^dFunctional Assessment of Cancer Therapy–Breast scores, modified; higher scores indicate better quality of life.

^eBrief Symptom Inventory; higher scores indicate more distress.

^fIntrusive Thoughts Scale; higher score indicates more distress.

\$30 per assessment; all assessments were completed in Spanish.

Measures

Using baseline data, we examined the psychometric properties of our primary outcome measures.

Breast cancer–specific quality of life. The Functional Assessment of Cancer Therapy–Breast (FACT-B) was our breast cancer–specific quality-of-life outcome measure²⁹; it has been translated into Spanish.³⁰ The FACT-B consists of 5 subscale scores pertaining to 4 well-being dimensions (physical, social–family, emotional, functional) and additional breast cancer concerns. A total overall score is the sum of all subscales. Women were asked the extent to which statements applied to them during the previous 7 days (response options: 0 = *not at all*, 1 = *a little bit*, 2 = *somewhat*, 3 = *quite a bit*, and 4 = *very much*).

Our psychometric analysis resulted in some modifications; of 37 items, 8 were dropped because of 1 or more problems: (1) low item-scale correlations (< 0.30 with other items in the scale corrected for overlap), (2) being conditional on having a partner and thus having a large amount of missing data, and (3) being conceptually different from other items on that scale. Subscales were scored by summing items after reversing some items; higher scores indicated greater well-being. Possible score ranges are as follows: physical well-being, 0–24; social–family well-being, 0–20; emotional well-being, 0–20; breast cancer

concerns, 0–28; and enjoyment of life, 0–16. The total FACT-B score was the sum of the 5 modified subscales (range = 0–108). In our sample, internal consistency reliabilities ranged from 0.69 to 0.84 for the subscales.

General distress symptoms. We used 3 scales from the Brief Symptom Inventory³¹: anxiety (e.g., feeling nervous, fearful), depression (e.g., feeling lonely, worthless), and somatization (e.g., dizziness, feeling weak). Women were asked how much each symptom had bothered them during the previous 7 days (response options: 0 = *not at all*, 1 = *a little bit*, 2 = *moderately*, 3 = *quite a bit*, or 4 = *extremely*). Scores were the mean of nonmissing items (possible range = 0–4); higher scores indicate more distress. In our sample, internal consistency reliabilities were 0.85 for anxiety, 0.83 for depression, and 0.76 for somatization.

Breast cancer–specific distress. We measured breast cancer distress with the 7-item Intrusive Thoughts Scale, a subscale of the revised Impact of Event Scale that is sensitive to change in women with breast cancer who are receiving a cognitive–behavioral intervention.¹³ Items were anchored to the breast cancer experience (as intended by the authors of the scale) and asked about ruminations related to their breast cancer, such as: “I had trouble falling asleep or staying asleep because of pictures or thoughts about my breast cancer that came into my mind.” Women were asked how often each symptom had applied to them in the past 7 days (response options: 0 = *not at all*, 1 = *rarely*, 2 = *sometimes*, and 3 = *often*). Using the

published scoring algorithm, we summed items after recoding responses to 0, 1, 3, and 5 (possible range = 0–35); higher scores indicate greater distress. Internal consistency reliability was 0.89.

Other variables. Descriptive characteristics included self-reported age, language acculturation (Marin short version³²), education, health insurance, employment status, financial hardship, ethnicity, national origin, US-born or foreign-born, marital status, self-rated health, and presence of other chronic medical conditions. Breast cancer characteristics verified through medical records review included cancer type, stage at diagnosis, and type of surgery and adjuvant treatment.

Randomization

The individual was the unit of randomization with 1:1 allocation to experimental groups. Randomization was stratified by recruitment site.

Before initiating recruitment, stratum-specific sequential identification numbers were generated and randomly preassigned in blocks of random sizes. After the baseline assessment, each participant was handed a sealed opaque envelope preprinted with the next sequential identification number from her stratum that revealed her group assignment.

Statistical Analysis

Using intention-to-treat analyses, we used repeated-measures linear regression models to estimate the intervention effects on study outcomes across the baseline, 3-month, and 6-month assessments. Likelihood-based model estimation assumed outcome responses were missing at random.³³ Explanatory variables included an intervention group indicator, a categorical time indicator, and a group × time interaction variable.

Custom contrasts estimated differences between treatment groups at each assessment as well as 2 group × linear time interactions: 1 examining the change from baseline to 3-month assessment (immediately after intervention) and 1 examining the change from baseline to 6 months. We compared experimental groups on primary outcomes of breast cancer–specific quality of life, general distress symptoms (anxiety, depression, somatization), and breast cancer–specific distress (intrusive thoughts).

TABLE 2—Quality of Life and Symptoms of Distress Among Spanish-Speaking Latinas With Breast Cancer, by Treatment Group at Baseline, 3 Months, and 6 Months: *Nuevo Amanecer* Study; San Francisco Bay Area, CA; February 2011–May 2014

	Intervention, Mean (SD)	Control, Mean (SD)	<i>P</i> ^a
Breast cancer-specific quality of life^b			
Physical well-being (scale 0–24)			
Baseline	15.29 (5.78)	16.76 (5.02)	.098
3 mo	18.13 (4.81)	18.01 (4.44)	.923
6 mo	19.44 (4.26)	18.44 (4.58)	.212
Treatment × time interaction (0–3 mo)			.151
Treatment × time interaction (0–6 mo)			.015
Social/family well-being (scale 0–20)			
Baseline	13.67 (4.42)	12.66 (4.25)	.154
3 mo	13.57 (4.65)	13.74 (4.24)	.732
6 mo	13.72 (4.81)	14.47 (3.81)	.293
Treatment × time interaction (0–3 mo)			.071
Treatment × time interaction (0–6 mo)			.025
Emotional well-being (scale 0–20)			
Baseline	12.07 (4.91)	12.86 (5.14)	.333
3 mo	15.93 (3.52)	14.73 (4.33)	.081
6 mo	16.39 (3.30)	14.89 (3.95)	.018
Treatment × time interaction (0–3 mo)			.018
Treatment × time interaction (0–6 mo)			.004
Breast cancer concerns (scale 0–28)			
Baseline	16.52 (5.43)	17.33 (5.08)	.344
3 mo	19.91 (4.69)	19.20 (4.69)	.396
6 mo	21.31 (3.83)	19.92 (5.22)	.083
Treatment × time interaction (0–3 mo)			.08
Treatment × time interaction (0–6 mo)			.013
Enjoyment of life (scale 0–16)			
Baseline	8.92 (3.80)	9.22 (3.43)	.61
3 mo	9.70 (3.59)	8.72 (3.28)	.103
6 mo	9.79 (3.39)	9.30 (3.06)	.41
Treatment × time interaction (0–3 mo)			.048
Treatment × time interaction (0–6 mo)			.267
Overall quality of life (scale 0–108)			
Baseline	66.46 (16.92)	68.83 (15.33)	.37
3 mo	77.24 (15.13)	74.39 (15.34)	.37
6 mo	80.64 (13.64)	77.02 (15.62)	.174
Treatment × time interaction (0–3 mo)			.061
Treatment × time interaction (0–6 mo)			.03
General symptoms of distress^c			
Anxiety (scale 0–4)			
Baseline	0.93 (0.84)	1.01 (0.88)	.577
3 mo	0.48 (0.66)	0.60 (0.73)	.32
6 mo	0.39 (0.53)	0.58 (0.76)	.09
Treatment × time interaction (0–3 mo)			.808
Treatment × time interaction (0–6 mo)			.465

*Continued***RESULTS**

We invited 195 women to the study; 22 were ineligible, and 22 refused to participate. We randomly assigned 151 women (77%) to the intervention (n = 76) or to the control group (n = 75) between February 2011 and November 2013; follow-up assessments occurred from May 2011 through May 2014 (Figure 1). More than 80% were enrolled within 6 months of diagnosis; almost half (47%) were enrolled within 3 months.

The sample had a mean age of 50 years (SD = 11), low levels of acculturation to English, low levels of educational attainment, and mostly public health insurance and was mostly unemployed; the majority had experienced financial hardship in the previous year (Table 1). All but 1 were immigrants; the majority were of Mexican origin (68%), followed by Central American (23%). About a third reported being in poor or fair health, and about half reported a comorbid chronic condition.

About three fourths of the women were diagnosed with invasive breast cancer, and the rest with ductal carcinoma in situ. The majority had breast-conserving surgery; 44% had a mastectomy. Almost 60% had chemotherapy, mostly followed by radiation therapy. Only 28% had radiation only, and 16% had no adjuvant treatment.

Baseline levels of breast cancer-specific quality of life were low, indicating poor quality of life. In general, symptoms of anxiety, depression, somatization, and intrusive thoughts were also low, indicating low levels of general distress (Table 1). We found no significant differences between intervention and control groups at baseline on demographics, clinical characteristics, quality of life, or distress outcomes (Table 1), indicating that balance between treatment groups was achieved with randomization.

Approximately 82% of intervention group participants were minimally compliant, completing at least 6 of 8 weekly sessions. Six-month study retention was excellent: 71 (93%) of the intervention group and 73 (97%) of the control group.

From baseline to 3-month follow-up, there were statistically significant treatment × time interaction effects for emotional well-being

TABLE 2—Continued

Depression (scale 0–4)			
Baseline	0.93 (0.84)	0.75 (0.76)	.164
3 mo	0.46 (0.59)	0.52 (0.63)	.531
6 mo	0.38 (0.48)	0.46 (0.62)	.355
Treatment × time interaction (0–3 mo)			.06
Treatment × time interaction (0–6 mo)			.045
Somatization (scale 0–4)			
Baseline	0.93 (0.78)	0.75 (0.59)	.104
3 mo	0.67 (0.65)	0.74 (0.63)	.558
6 mo	0.52 (0.51)	0.66 (0.60)	.162
Treatment × time interaction (0–3 mo)			.038
Treatment × time interaction (0–6 mo)			.005
Breast cancer-specific distress^d			
Intrusive thoughts scale (scale 0–35)			
Baseline	7.96 (8.46)	8.65 (8.91)	.625
3 mo	5.46 (7.52)	7.04 (8.00)	.232
6 mo	3.87 (5.79)	6.27 (8.42)	.046
Treatment × time interaction (0–3 mo)			.589
Treatment × time interaction (0–6 mo)			.226

^aGroup means were compared at each assessment. Treatment × time interaction from baseline to 3-month assessment is shortly after completing the intervention; treatment × time interaction from baseline to 6-month assessment is 3 months after intervention.

^bFunctional Assessment of Cancer Therapy–Breast scores, modified; higher scores indicate better quality of life.

^cBrief Symptom Inventory; higher scores indicate more distress.

^dIntrusive Thoughts Scale; higher score indicates more distress.

($P=.018$), enjoyment of life ($P=.048$), and somatization ($P=.038$) and trends toward significance for breast cancer concerns ($P=.08$), the total score (overall quality of life; $P=.061$), and depression ($P=.06$; Table 2). From baseline to 3 months, the intervention group improved significantly more than the control group on quality of life and distress: emotional well-being, +3.86 versus +1.87 points (range=0–20; Figure 2); enjoyment of life, +0.78 points vs –0.50 points (range=0–16); and somatization, –0.26 vs –0.01 points (range=0–4).

From baseline to 6-month follow-up (3 months after intervention), we found significant treatment × time interaction effects for physical well-being ($P=.015$), social–family well-being ($P=.025$), emotional well-being ($P=.004$), breast cancer concerns ($P=.013$), overall quality of life ($P=.03$), depression ($P=.045$), and somatization ($P=.005$). From baseline to 6 months, the intervention group improved significantly more than the control group on quality of life and distress: physical well-being, +4.15 versus +1.68 points (range=0–24; Figure 2);

emotional well-being, +4.32 versus +2.03 points (range=0–20; Figure 2); breast cancer concerns, +4.79 points versus +2.59 points (range=0–28); overall quality of life, +14.18 versus +8.19 points (range=0–108); depression, –0.55 versus –0.29 points (range=0–4); and somatization, –0.41 versus –0.09 points (range=0–4). All significant interaction effects were in the hypothesized direction of better quality-of-life improvements in the intervention than in the control group, except for social–family well-being. From baseline to 6 months, the control group improved significantly more than the intervention group on social–family well-being (+0.05 vs +1.81 points; range=0–20).

Regarding group main effects, at 6 months the group mean for emotional well-being was significantly higher for the intervention than the control group, indicating better quality of life (16.39 vs 14.89; $P=.018$). Although we observed no significant treatment × time interaction effects for anxiety or intrusive thoughts, the group mean on intrusive thoughts at 6 months was significantly lower for the

intervention group than the control group, indicating less distress (3.87 vs 6.27; $P=.046$).

DISCUSSION

In this community-based peer-delivered translational trial of a CBSM intervention for Spanish-speaking Latinas with breast cancer, we achieved excellent study retention and program participation and clinically significant improvements in several HRQOL dimensions. Compared with the usual-care control group, women who received the intervention reported significant improvements at 6 months in breast cancer–specific physical well-being, emotional well-being, breast cancer concerns, and overall quality of life as well as significant reductions in general symptoms of depression and somatization.

Minimally important differences for the FACT-B measures of breast cancer–specific quality of life, that is, differences that are important to patients, have been estimated on the basis of 2 studies of White women with metastatic breast cancer.³⁴ These estimates suggest that improvements of 2 to 3 points on breast cancer concerns and of 7 to 8 points on FACT-B total scores are minimally important differences. Differences in improvements from baseline to 6 months between intervention and control group women in our study were about this magnitude, suggesting that minimally important differences were achieved if one can extrapolate from these previous studies conducted in different ethnic and clinical populations.³⁴ However, it would be preferable to identify minimally important differences specifically for Latinas with breast cancer.

It is interesting that some of the greatest improvements occurred in somatization. This is an important outcome for Latinas because somatization may be a more culturally acceptable way to express psychological distress because of the stigma associated with mental health issues. For example, a validation study of the Patient Health Questionnaire-15, which assesses somatic complaints in primary care, found that among Latinos, the questionnaire captured mostly psychiatric distress, whereas among non-Latinos it was equally associated with psychiatric distress and a history of medically unexplained symptoms.³⁵ Thus, for Latinos, somatization measures may be especially sensitive

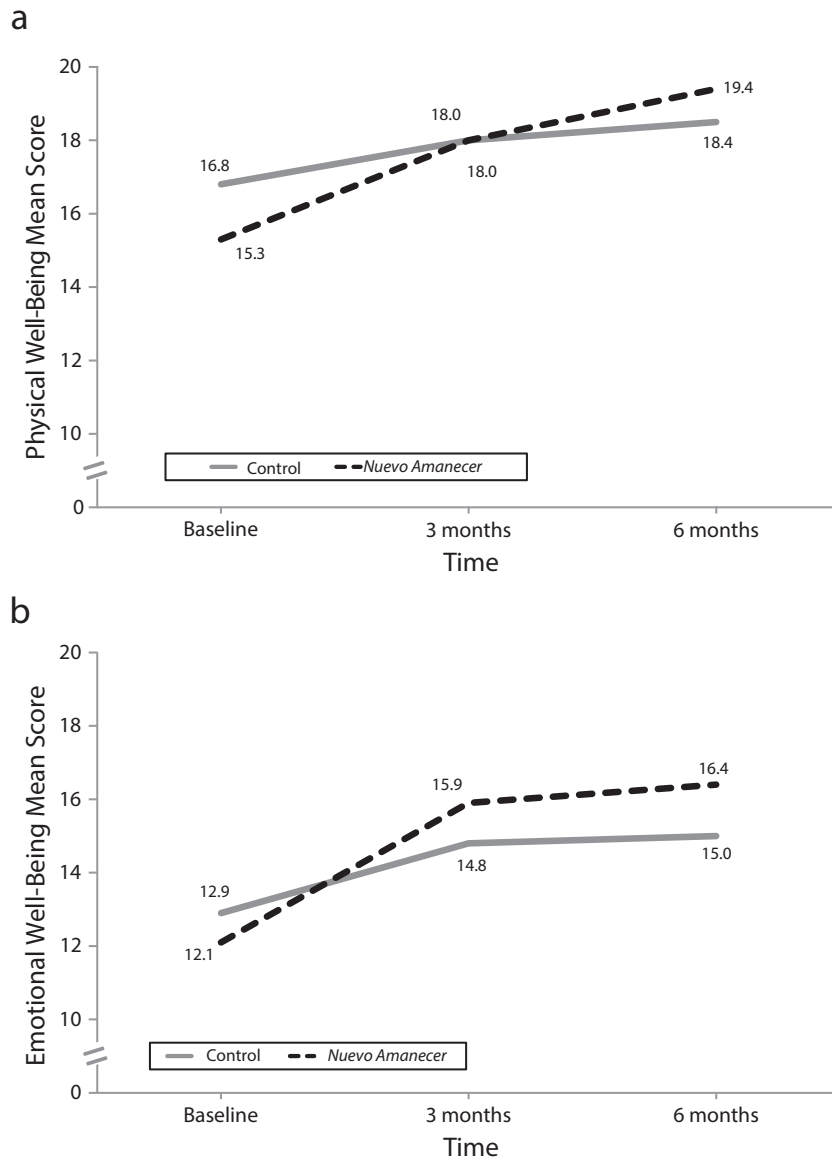


FIGURE 2—Mean differences between *Nuevo Amanecer* and control groups in (a) physical well-being and (b) emotional well-being: San Francisco Bay Area, CA; February 2011–May 2014.

outcomes to include in intervention trials that aim to improve quality of life and psychosocial health.

We found no significant differences between treatment groups in changes over time in intrusive thoughts about breast cancer; however, at 6 months, the treatment group reported significantly less distress than the control group. The lack of a significant interaction effect is counter to previous psychosocial intervention trials, including similar types

of cognitive–behavioral interventions conducted with samples of predominantly White women with breast cancer, which found significant improvements on this outcome over time.^{13,36} Cultural factors might help explain why we did not observe such changes in our Latina sample. It is well documented that traditional Latinos have a strong tendency to equate cancer with death.^{37,38} Fatalistic beliefs may be so embedded among Latina women

that stress management interventions are insufficient to achieve significant reductions in intrusive thoughts over time without special emphasis on managing fears of recurrence and death. In fact, when we shared our results with Latina breast cancer survivors, they stated that this fear of death never goes away and manifests as ongoing fears of recurrence.

The intervention group unexpectedly demonstrated worse social–family well-being than the control group. A potential explanation is that women who were in the intervention group became more confident in expressing their needs and asking for help from partners, family members, and friends. The program included instruction in communicating with family and friends about cancer, how to ask for help, and expressing feelings and needs because our formative work indicated the need to teach traditional Latinas to be more assertive because they may defer to their partners and hide their needs to protect their families.²² If Latina women were more expressive of their needs as a result of the intervention, this may have disrupted customary social interactions and might explain the lower ratings of social and family well-being. Interventions that target the family unit may perhaps help prevent these lower ratings.

Using community-based participatory research methods and social-cognitive theory, we designed the *Nuevo Amanecer* program to enhance its cultural relevance for Spanish-speaking Latinas with breast cancer who suffer disparities in HRQOL and psychosocial health compared with White women. *Nuevo Amanecer* is the only community-based translation of a CBSM program for Spanish-speaking Latinas with breast cancer, and it thus makes a substantial contribution to efforts to address these disparities. Another study among 52 Latinas with breast cancer tested a psychoeducational intervention to facilitate posttreatment survivorship, but the investigators did not differentiate between English- and Spanish-speaking Latinas and did not find significant improvements in quality-of-life outcomes.³⁹ The greater improvements in our study could be the result of intervening earlier in the survivorship continuum of care, training in cognitive–behavioral stress management skills that can be applied across quality-of-life domains, intervention delivery by peers, or other study design and implementation factors.

We achieved an overall study retention rate of 95%, indicating that Latinas with breast cancer are willing and able to participate in cancer clinical trials during the first year after their diagnosis. Most improvements attributed to the intervention occurred at 6 months. However, emotional well-being, enjoyment of life, and somatization were significantly different at 3 months, and the 3 other outcomes showed trends toward significant improvements. These results suggest that women may need time to practice the stress management skills before their HRQOL is affected. It is possible that lengthening the intervention from 8 to 12 weeks would have a stronger impact.

Limitations

The study has limitations. Our sample consisted of mostly Mexican and Central American Latinas and may not generalize to other Latino groups. Although we sampled women from 5 Northern California counties, settings tended to be urban; findings may not generalize to Latinas living in other US regions or rural areas.

Conclusions

Our community-based translational study demonstrated significant improvements in several HRQOL dimensions of vulnerable cancer survivors at higher risk for psychosocial morbidity and poorer quality of life. Cultural and linguistic adaptation of evidence-based CBSM interventions for Latinas with breast cancer helped address their psychosocial health needs. Peer-delivered programs are a promising approach to address ethnic and language disparities in psychosocial breast cancer outcomes and have great dissemination potential. This practical program could be adopted by other community-based organizations to reach Latinas and fills a large gap because most CBSM-type programs are delivered in English in clinical settings by professional staff. ■

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Contributors

With input from all coauthors, A. M. Nápoles and C. Ortiz designed and oversaw all aspects of the project. J. Santoyo-Olsson participated in the design of the trial and intervention, supervised field staff, and completed data analysis. A. L. Stewart participated in the design of the study, psychometric analyses of the measures, data analysis plans, and interpretation of the data. S. Gregorich participated in the design of the trial and interpretation of the results and completed data analysis. H. E. Lee, Y. Durón, P. McGuire, and J. Luce assisted with the design of the intervention, implementation of the study, and interpretation of results. All authors cowrote and edited the article and approved the final version.

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Human Participant Protection

This study protocol was approved by the University of California, San Francisco, Committee on Human Research and the Mills-Peninsula Health Services and San Mateo Medical Center Clinical Research Committee. Participants provided written informed consent.

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