The BCPT Symptom Scales: A Measure of Physical Symptoms for Women Diagnosed With or at Risk for Breast Cancer

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Background: **Documentation of concurrent and late side effects of medical interventions to prevent and treat breast cancer is important in research and clinical practice. We used the Breast Cancer Prevention Trial (BCPT) Symptom Checklist to develop an instrument (BCPT Symptom Scales) that could be used to assess side effects and to examine correlates of the derived symptom dimensions among patient populations.** ***Methods:*** **Exploratory and confirmatory factor analyses were conducted using data from the 42-item BCPT Symptom Checklist completed by four distinct patient populations (N = 2208) who had previously been diagnosed with breast cancer or were at risk for the disease. We examined associations among the resulting BCPT Symptom Scales and demographic and cancer-related variables and a widely used measure of health-related quality of life.** ***Results:*** **Exploratory and confirmatory factor analyses revealed eight factors corresponding to physical symptoms associated with cancer treatment, chemoprevention, menopause, and normal aging: hot flashes, nausea, bladder control, vaginal problems, musculoskeletal pain, cognitive problems, weight problems, and arm problems. On the derived BCPT Symptom Scales, women reported somewhat higher mean scores on scales for hot flashes, pain, and weight problems than on scales for the other symptoms. Demographic and cancer-related variables accounted for up to 15% of the interindividual variance in how women responded to the symptom scales. The most consistent predictors of reporting greater symptoms included lower education level and previous receipt of chemotherapy.** ***Conclusions:*** **Meaningful symptom dimensions, identified across four samples of women, were associated with demographic and breast cancer–related variables. The BCPT Symptom Scales offer a valuable refinement of the original BCPT Symptom Checklist to assess side effects associated with the treatment and prevention of breast cancer. [J Natl Cancer Inst 2005;97:448–56]**

Health-related quality of life (HRQOL) is a multidimensional construct that captures the subjective assessment of physical, emotional, and social well-being of individuals through data collection with psychometrically validated questionnaires *(1–3)*. During the past two decades, the frequency of including HRQOL assessments in a variety of research and clinical settings, especially clinical trials, has increased *(4–7)*. Moreover, cancer researchers have developed symptom checklists and condition-specific questionnaires to identify important aspects of health and functioning that may be affected by cancer and its treatment *(8–11)*. Indeed, the content areas of these more specific questionnaires are often more relevant to the outcomes of the treatment being studied than the more general HRQOL instruments and may cover the most critical areas for patients and individuals considering preventive interventions *(12–14)*.

The number of breast cancer patients and survivors is growing *(15)*, and the role for chemoprevention in women at high risk for breast cancer is expanding *(16,17)*. Thus, it is important for patients, researchers, and clinicians to assess accurately the occurrence of concurrent and late side effects of medical interventions to treat and prevent breast cancer. Information about side effects may be critical for preparing women for the physical sequelae of treatment and can help women to then make informed medical decisions *(18)*. Thus, development of a standardized brief instrument to assess the common physical side effects of treatment would enable comparisons across samples, interventions, and time in breast cancer patients and women at risk for the disease.

In 1991, at the time of the development of the protocol for the placebo-controlled tamoxifen National Surgical Adjuvant Breast

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and Bowel Project (NSABP) Breast Cancer Prevention Trial (BCPT) *(11)*, the quality of life committee for the study selected a number of validated questionnaires to examine HRQOL outcomes in the trial, with a particular focus on measures that were considered appropriate for healthy midlife and aging women. In addition, there was special interest in capturing the common physical and psychological symptoms associated with both menopause and the known side effects of tamoxifen. The investigators adapted items from several existing questionnaires of menopausal symptoms that were in use in ongoing clinical trials and extant research in healthy postmenopausal women [see *(11)* for details]. The resulting 42-item questionnaire, called the BCPT Symptom Checklist, was used successfully in the BCPT *(13)*. Baseline analyses of single items revealed that the presence and level of symptoms varied with participant age *(11)*. In addition, women randomly assigned to take tamoxifen were subsequently found to be more likely to experience vasomotor symptoms (i.e., hot flashes, cold sweats, and night sweats), vaginal discharge, and genital itching than were women randomly assigned to placebo *(13,16)*.

By using the descriptive data from the BCPT population for comparison *(13)*, Ganz et al. *(18–21)* have also used the BCPT Symptom Checklist in studies of breast cancer patients and survivors. The BCPT Symptom Checklist also is being used in other ongoing studies of prevention and treatment within the NSABP *(22)*. However, investigators typically report analyses on single items of the instrument, which often are less reliable and less valid representations of symptom dimensions than are scales that include multiple items. Furthermore, conducting analyses on numerous single items is more likely to result in false-positive (i.e., concluding that an effect exists when it actually does not) errors than is analyzing fewer, multi-item symptom scales. To our knowledge, there has been no published attempt to construct conceptually meaningful and psychometrically adequate multi-item scales representing the symptom dimensions assessed in individual items of the BCPT Symptom Checklist.

In this study, we examined the psychometric properties of the BCPT Symptom Checklist across four relevant samples of women. Women in these samples had completed the BCPT Symptom Checklist as part of independent, larger research studies. The women were categorized as follows: sample 1, breast cancer survivors participating in a study of HRQOL and sexuality *(19)*; sample 2, breast cancer survivors aged 50 or younger at diagnosis and involved in a study of HRQOL and reproductive health from the Cancer and Menopause Study *(20)*; sample 3, women beginning a psychoeducational trial after treatment for breast cancer in the Moving Beyond Cancer trial *(18)*; and sample 4, women at high risk for breast cancer initiating a chemoprevention trial *(23)*.

Our goals were to determine the factor structure (i.e., to identify meaningful symptom clusters) of the instrument, to eliminate items that did not form coherent symptom constellations, and to assess between-sample differences on the newly formed symptom scales (within-sample analyses of items are reported in the original manuscripts by each separate study group). Furthermore, to assess whether the scales were distinct from measures of HRQOL (i.e., whether they possessed discriminant validity), we correlated the resulting scales with a widely used measure of HRQOL *(24)*. Finally, we examined associations among the developed symptom scales and demographic (i.e., age, ethnicity, education, and marital status) and cancer-related (i.e., time since diagnosis, chemotherapy receipt, surgery type, and tamoxifen use) variables. We chose those variables because they were likely to be associated with symptoms and because they were assessed using metrics easily aligned across the four samples. Because women in sample 3 recently had completed medical treatment for breast cancer and on average were older than the other participant samples, we expected women from sample 3 to have a more marked symptom profile than women in the other samples, especially those in sample 4, which comprised women at risk for, but not diagnosed with, breast cancer. We also expected demographic and cancer-related variables to account for at least part of the differences between samples. Specifically, we anticipated that a greater number of symptoms would be associated with being older than with being younger (e.g., bladder control, vaginal dryness, and forgetfulness), being more recently diagnosed with breast cancer than being diagnosed longer ago (e.g., difficulty concentrating), and receiving chemotherapy or tamoxifen than not receiving such drugs (e.g., hot flashes, weight gain).

Samples and Methods

In each of the four study samples, women completed the BCPT Checklist as part of the original study's protocol. Methods of recruitment for the original studies are summarized below.

Sample 1

Sample 1 participants consisted of 863 women who were diagnosed with stage 0–II breast cancer 1–5 years earlier and participating in a descriptive study of quality of life *(19)*. Participants were recruited primarily through tumor registries via invitation letters with subsequent follow-up phone calls. Participants completed a mailed questionnaire packet that included the BCPT Symptom Checklist.

Sample 2

Sample 2 participants consisted of 577 women who were aged 49 years or younger at diagnosis of stage 0–II breast cancer and who had been disease free for 2–10 years *(20)*. The women were recruited for a study of quality of life and health outcomes in younger breast cancer survivors *(20)* by using lists from two tumor registries. Under physicians' letterhead, women were mailed an invitation letter and responded by letter or were called by research staff to determine eligibility and interest in participation. Those who agreed to participate were then mailed a questionnaire packet that included the BCPT Symptom Checklist.

Sample 3

Sample 3 participants consisted of 560 women who had recently completed medical treatment for stage I or II invasive breast cancer and who had completed a baseline assessment for a multisite, randomized, controlled trial of a psychoeducational intervention for women making the transition from active medical treatment to survivorship *(18)*. Potentially eligible patients were sent an invitation under their physicians' letterhead, which was followed by a telephone call to explain the nature of the study. Participants were tracked until they completed primary medical treatments (i.e., surgery, chemotherapy, and/or radiotherapy), whereupon they completed the BCPT Symptom Checklist as part of a mailed baseline questionnaire packet.

Sample 4

Sample 4 participants consisted of 208 women who were at risk for, but not diagnosed with, breast cancer as determined by having breast hyperplasia with atypia (or without atypia but with an additional indication of high risk, such as a known BRCA1 and/or BRCA2 mutation) *(23)*. Participants were recruited from a high-risk clinic for breast cancer by research staff for a randomized, controlled chemoprevention trial. They completed the BCPT Symptom Checklist as part of a mailed baseline questionnaire packet for the trial.

Measures

As part of an assessment package specific to each investigation *(18–20,23)* and with approval of local institutional review boards, women completed the BCPT Symptom Checklist *(11,13)*, which comprises a list of 42 physical and psychological symptoms (e.g., vaginal dryness, hot flashes, short temper) that are relevant to women in cancer treatment or chemoprevention trials. For two samples (samples 2 and 3), two items (arm swelling [lymphedema] and decreased range of motion in arm on surgery side) were added to assess arm problems resulting from treatment.

For samples 1 and 2, women rated how much they were bothered by each of the 42 symptoms during the past 4 weeks on a 5-point severity scale (0 = not at all; 1 = slightly; 2 = moderately; 3 = quite a bit; 4 = extremely). For samples 3 and 4, women first were instructed to mark yes or no with regard to whether they had experienced each of the 42 symptoms within the past 4 weeks, the format for the BCPT Symptom Checklist used in the original BCPT study *(11,13)*, and then to rate the severity of those symptoms they had experienced on the 5-point scale. For items marked no, the severity rating for that item was 0.

Women from samples 1, 2, and 3 also completed the Medical Outcomes Study Short Form-36 (SF-36) *(24)*, a measure of HRQOL. In addition to eight specific subscales, the SF-36 measure has two summary scales *(25)*, the Physical Component Summary (PCS) and the Mental Component Summary (MCS), which were used in the present analyses.

Statistical Analysis

Sample 1 was the largest of the four samples and likely to be the most representative of early-stage breast cancer patients because these patients were recruited from tumor registries with no age restriction for those recruited. Thus, we first conducted exploratory factor analysis on the 42 BCPT items by using data from that sample. Exploratory factor analysis is a common method to discover the underlying factors in a set of variables or items. We used principal axis factoring on the correlation matrix, which seeks the fewest number of factors that can account for most of the common variance in a set of variables *(26)*, followed by quartimin rotation to allow for correlated factors *(26)*. The number of factors was determined through parallel analysis (i.e., an augmented version of the scree plot) *(27)*. To derive meaningful factors, we examined the factor loadings (i.e., correlation coefficients between the item and the factor, which assume values between –1 and +1).

We performed confirmatory factor analyses on the other three samples by using the factor pattern from the exploratory factor analysis to designate a priori the items expected to form specific factors. Confirmatory factor analyses were conducted using the maximum-likelihood method in Mplus version 3.11 *(28)*. Four goodness-of-fit indices were computed: CFI (comparative fit index), TLI (Tucker-Lewis Index), RMSEA (root mean-squared error of approximation), and SRMR (standardized root mean-squared residual). We used the cutoffs recommended by Hu and Bentler *(29)*: for CFI and TLI, 0.95 or greater; for RMSEA, less than 0.06; and for SRMR, less than 0.08.

We then formed scales on the basis of the factor-analytic findings and computed descriptive statistics, internal consistency estimates of reliability (Cronbach's coefficient α), and intercorrelations among the scales. We compared scale scores across samples by using analyses of variance and follow-up Tukey tests, with the study sample as the four-level independent variable (or two levels for arm problems) and symptom scale scores as the dependent variables. Because scale distributions were skewed toward low scores, we also conducted these analyses on log-transformed scale scores. The results of both analyses were similar; thus, nontransformed means are reported along with bias-corrected and accelerated bootstrap confidence intervals *(30)* that do not rely on distributional assumptions.

We examined relationships between each scale and the SF-36 scale by using Pearson's product-moment correlations and between each scale and available demographic and cancer-related variables through hierarchical multiple linear regressions that included those variables that were observed across samples. Explanatory variables were entered in three blocks, with change in R^2 computed for each block. First, demographic variables (i.e., age, marital status, ethnicity, and education level) were entered. Second, cancer-related variables (i.e., time since diagnosis, surgery type, chemotherapy receipt, and current tamoxifen use) were added. Third, indicators for the specific samples were entered to assess whether the obtained between-sample differences were statistically significant after accounting for demographic and cancer-related variables. Exploratory factor analysis and all other statistical analyses were performed with S-PLUS version 6.2 (Insightful Corporation, Seattle, WA). All statistical tests were two-sided.

Results

Descriptive Statistics

Descriptive statistics on the demographic and treatment-related variables for the four samples are shown in Table 1. In general, the majority of women from the four samples were white, highly educated (i.e., college education or higher degree), and married. The samples showed substantial variation in the time since cancer diagnosis, chemotherapy receipt, and tamoxifen use.

Exploratory Factor Analysis on BCPT Items in Sample 1 Participants

Exploratory factor analysis suggested that a seven-factor solution of hot flashes, nausea, bladder control, vaginal problems, musculoskeletal pain, cognitive problems, and weight problems best characterized the data, as indicated by high factor loadings (>.60) on the items' respective factors and relatively low loadings (<.30) on all other factors. Correlations

Table 1. Descriptive statistics for demographic and cancer-related variables for the four samples of women previously diagnosed with or at high risk for breast cancer

Variable	Sample 1 (n = 863)	Sample 2 (n = 577)	Sample 3 (n = 560)	Sample 4 (n = 208)*
Mean age, y (SD, range)	56 (11.5, 31–88)	50 (5.6, 30–62)	57 (11.4, 27–87)	47 (7.3, 20–66)
Ethnicity, %				
White	77	70	86	96
Black	14	12	7	3
Other	9	16	7	1
Education level (% college degree)	49	61	63	59
Marital status (% married)	62	64	63	83
Time since diagnosis, mo (range)	36 (10–78)	71 (18–140)	7 (1–19)	NA
Chemotherapy (% of patients received)	38	62	50	NA
Surgery (% of patients with lumpectomy)	51	56	67	NA
Tamoxifen (% of patients with current use)	47	18	54	0

*NA = not applicable.

between quartimin-rotated common factors ranged from −0.42 to 0.43 (median = −0.12). Estimated communalities (i.e., proportion of item variance explained by the seven factors, which assumes values between 0 and 1) ranged from 0.41 to 0.88 (median = 0.63). The items, factor loadings, and percentage of variance explained for each of the seven factors are shown in Table 2.

The seven factors conformed to symptom clusters associated with breast cancer treatment (e.g., hot flashes, nausea, cognitive problems), chemoprevention (e.g., hot flashes, vaginal problems), the experience of menopause (e.g., hot flashes, vaginal problems), or normal aging (e.g., musculoskeletal pain, cognitive problems). An additional weak factor comprised of three items (vaginal discharge, genital itching and/or irritation, and vaginal bleeding or spotting) emerged, with factor loadings of less than 0.45. In addition, an exploratory factor analysis, which included the two items about arm problems and the items for the other seven factors, conducted with combined samples 2 and 3 revealed that the two arm problem items formed an eighth factor (Table 2).

The 26 items that did not load on any factor are listed in the Table 2 footnote. The items appear to represent symptoms (e.g., ringing in ears, tendency toward accidents) that are not associated strongly or consistently with cancer treatment, chemoprevention, menopause, or normal aging.

Confirmatory Factor Analysis on BCPT Items in Samples 2, 3, and 4

Confirmatory factor analyses were conducted on data from samples 2, 3, and 4 on the items forming seven coherent factors in the exploratory analysis for sample 1. Postulated factors and their respective items were identical to those obtained in sample 1, with

Table 2. Exploratory factor analysis for the BCPT Symptom Checklist on breast cancer survivors from sample 1 (n = 863)*

Item	Hot flashes	Nausea	Bladder control	Vaginal problems	Musculoskeletal pain	Cognitive problems	Weight problems	Arm problems†
Hot flashes	.82							
Night sweats	.82							
Nausea		.73						
Vomiting		.76						
Difficulty with bladder control (when laughing or crying)			.75					
Difficulty with bladder control (at other times)			.77					
Vaginal dryness				.81				
Pain with intercourse				.82				
General aches and pains					.82			
Joint pains					.84			
Muscle stiffness					.70			
Forgetfulness						.61		
Difficulty concentrating						.93		
Easily distracted						.90		
Weight gain							.71	
Unhappy with the appearance of my body							.63	
Arm swelling (lymphedema)								.70
Decreased range of motion in arm on surgery side								.77
% Variance explained by factor (total = 61.8 %)	8.5	7.0	7.3	8.4	11.8	13.0	5.8	

*The sample was recruited from reference *(19)*. The factor extraction was conducted using principal axis factoring *(26)* followed by quartimin rotation. Items with loadings of less than 0.60 on any factor were headaches, blind spots and/or fuzzy vision, diarrhea, constipation, vaginal discharge, vaginal bleeding or spotting, genital itching and/or irritation, cramps, breast sensitivity and/or tenderness, ringing in ears, chest pains, swelling of hands or feet, difficulty breathing, dry mouth, weight loss, decreased appetite, feelings of suffocation, excitability, short temper, tendency to take naps and/or stay in bed, cold sweats, tendency toward accidents, avoidance of social affairs, dizziness and/or faintness, numbness and/or tingling, and early awakening.

†Arm problem items were administered to only sample 2 *(20)* and sample 3 *(18)* as described in the text, and factor loadings were based on exploratory factor analysis of those two samples combined, extracting a total of eight factors.

Table 3. Model fit indices for confirmatory factor analyses for symptom scale scores for women from samples 2, 3, and 4*

Sample	TLI	CFI	RMSEA (90% CI)†	SRMR
Sample 2	0.98	0.99	0.033 (0.02 to 0.04)	0.03
Sample 3	0.93	0.95	0.056 (0.05 to 0.06)	0.04
Sample 4	0.96	0.98	0.038 (0.00 to 0.06)	0.05

*Confirmatory factor analyses were conducted by using the maximum-likelihood method in Mplus *(28)*. Women in sample 2 were recruited from the study group described in reference *(20)*. Women in sample 3 were recruited from the study group described in reference *(18)*. Women in sample 4 were recruited from the study group described in reference *(23)*.

†CI = confidence interval.

the exception that the item "vomiting" on the nausea factor occurred with such low frequency (<5% of the women in any sample had a score greater than 0) that no estimates could be obtained in the confirmatory factor analyses. Thus, the nausea and vomiting items were deleted from analyses of the three samples.

Indices indicating model fit for the three samples are shown in Table 3. Fit indices were quite good, exceeding the criteria for model fit *(29)* on CFI, RMSEA, and SRMR in all three samples and exceeding the recommended criterion for TLI in samples 2 and 4. Goodness-of-fit indices for sample 3 were slightly lower than those of the other samples. Thus, the postulated symptom scales generally fit the data well.

Descriptive Statistics, Internal Consistency Estimates of Reliability, and Between-Sample Intercorrelations and Comparisons

To further examine the psychometric properties of the obtained item sets, we first formed symptom scales by averaging the scores on items forming each factor and then created a total mean score by averaging scores across all items. Descriptive statistics on the eight BCPT Symptom Scales and total score are shown in Table 4. On average, women reported being bothered "not at all" to "slightly" over the past 4 weeks by the symptoms. However, on specific scales (i.e., hot flashes, musculoskeletal pain, weight problems), women in some samples reported being "slightly" to "moderately" bothered by the symptoms, on average.

Table 5 shows the internal consistency estimates of reliability (Cronbach's coefficient α) and intercorrelations for the eight scales and total score for all samples combined. (These coefficients were also examined for each sample separately, and findings [data not shown] were very similar across samples.) The scales' internal consistencies were adequate for research purposes, although they were somewhat low (α < .70) for nausea and weight problems. The Cronbach's α for all items combined from the seven factors (excluding arm problems) was 0.81. In general, BCPT symptom scales were modestly correlated such that nearly all correlations were less than r = 0.30. The only correlations exceeding 0.30 were those among musculoskeletal pain, cognitive problems, and weight problems.

Analyses of variance were conducted to determine between-sample differences on the BCPT Symptom Scales. These analyses revealed that only nausea scores did not vary statistically significantly across samples, with very low mean scores on that scale (Table 4). Although statistically significant group differences were obtained on seven of the eight scales, the associated effect sizes were small *(31)*. Follow-up Tukey tests for between-group comparisons revealed that the hot flash mean score was statistically significantly higher in sample 3, the group that had completed medical treatments for breast cancer most recently, than in the other samples. Bladder control problems were statistically significantly more bothersome for sample 1 and 4 participants than for participants in the other samples, and vaginal problems were more severe for sample 2 participants than for participants in the other samples. Musculoskeletal pain was reported as more bothersome by sample 1 and 3 participants than by those in the other samples. The total mean symptom score, cognitive problems score, and weight problems score were statistically significantly less bothersome for sample 4 participants, the group at risk for breast cancer, than for participants in the other samples. Arm problems were reported as more severe by women in sample 2 than by those in sample 3, which is consistent with the longer time since surgery for sample 2 participants.

Correlations of the BCPT Symptom Scales With the SF-36

To provide a preliminary examination of the BCPT Symptom Scales' discriminant validity, we correlated the scale scores with the SF-36 MCS and PCS scores. Magnitudes of the correlations were similar across samples 1, 2, and 3 and for those samples combined (Table 6). The BCPT Symptom Scales were modestly

Table 4. Descriptive statistics and analyses of variance on the BCPT Symptom Scales for the four samples

Scale	Average scale mean (95% confidence interval)* for samples: 1 (n = 863)	2 (n = 577)	3 (n = 560)	4 (n = 208)	*P*	Effect size Cohen's f
Hot flashes	0.99_b (0.92 to 1.06)	0.94_b (0.86 to 1.03)	1.22_a (1.13 to 1.32)	0.50_c (0.42 to 0.60)	<.001	0.03
Nausea	0.14_a (0.11 to 0.17)	0.16_a (0.13 to 0.20)	0.17_a (0.14 to 0.21)	0.14_a (0.09 to 0.22)	.478	0.00
Bladder control	0.52_a (0.47 to 0.58)	0.38_b (0.33 to 0.43)	0.32_b (0.28 to 0.38)	0.40_{ab} (0.31 to 0.50)	<.001	0.01
Vaginal problems	0.71_b (0.64 to 0.78)	0.88_a (0.79 to 0.98)	0.49_c (0.41 to 0.56)	0.29_c (0.22 to 0.38)	<.001	0.03
Musculoskeletal pain	1.11_a (1.05 to 1.17)	0.84_b (0.77 to 0.92)	1.06_a (0.98 to 1.14)	0.77_b (0.67 to 0.87)	<.001	0.02
Cognitive problems	0.77_a (0.72 to 0.82)	0.76_a (0.69 to 0.82)	0.73_a (0.66 to 0.81)	0.42_b (0.33 to 0.51)	<.001	0.02
Weight problems	1.04_a (0.98 to 1.11)	1.10_a (1.02 to 1.18)	0.98_a (0.90 to 1.06)	0.71_b (0.60 to 0.82)	<.001	0.01
Arm problems		0.53_a (0.47 to 0.60)	0.34_b (0.30 to 0.40)		<.001	0.02
Total score	0.78_a (0.74 to 0.81)	0.73_a (0.69 to 0.77)	0.73_a (0.69 to 0.77)	0.48_b (0.43 to 0.53)	<.001	0.03

*Average scale means (95% bootstrap confidence intervals) for each of the data sets for scoring options 0 (not at all), 1 (slightly), 2 (moderately), 3 (quite a bit), and 4 (extremely). The total score was calculated from the seven scales completed by all four samples. Means with different subscripts differ significantly between samples at $P<.05$ based on follow-up Tukey tests after analysis of variance (i.e., means with $_a$ are statistically significantly greater than means with $_b$, which are statistically significantly greater than means with $_c$; and $_{ab}$ indicates that the mean falls between those indicated by $_a$ and $_b$ but does not differ statistically significantly from either mean).

Table 5. Intercorrelations for and Cronbach's coefficient α on the BCPT Symptom Scales for four samples (n = 2208)*

Item	Hot flash	Nausea	Bladder control	Vaginal problems	Musculoskeletal pain	Cognitive problems	Weight problems	Arm problems
Hot flash	0.83							
Nausea	0.10	0.65						
Bladder control	0.09	0.05	0.73					
Vaginal problems	0.20	0.03	0.11	0.79				
Musculoskeletal pain	0.28	0.16	0.26	0.14	0.82			
Cognitive problems	0.24	0.20	0.21	0.20	0.37	0.85		
Weight problems	0.26	0.12	0.21	0.12	0.34	0.36	0.59	
Arm problems	0.10	0.13	0.24	0.11	0.28	0.19	0.29	0.72

*Coefficients on the diagonal are Cronbach's α for each scale. Cronbach's α for all items combined was 0.81. Coefficients below the diagonal are Pearson's product-moment correlations between BCPT Symptom Scales. For arm problems, all coefficients are for combined samples 2 and 3 only (n = 1137).

negatively correlated with the SF-36 scales, with only two scale correlations exceeding r = 0.30. The BCPT Total Score was moderately correlated with the SF-36 scales.

Predictors of BCPT Symptom Scale Scores

Hierarchical linear regressions on the three samples in which all women had been diagnosed with breast cancer were conducted to examine the set of cancer-related and demographic predictors of each BCPT Symptom Scale score. For the regressions, we used the coding categories listed in Table 7. Because the experience of menopause might produce a curvilinear relation between age and some of the scales (e.g., hot flashes) *(32)*, we included a quadratic age term in addition to a linear term for age in the regressions. Regression analyses conducted with all four samples and including only the set of demographic predictors produced similar associations between those predictors and the symptom scales.

Results of linear regressions, including beta values and associated 95% confidence intervals and *P* value for each predictor, and the change in R^2 as each set of predictors was entered in the regression equation, are shown in Table 7. The sets of predictors, when combined, accounted for 2% to 15% of the variance in each of the BCPT Symptom Scales. With regard to individual predictors, statistical significance of the quadratic age component for the hot flash scale was the result of higher symptom reporting by women at aged 50 to 55 years, with fewer symptoms reported by younger and older women. Vaginal problems were reported most often by women aged 60 to 65 years, with younger and older women less likely to report those symptoms. Musculoskeletal pain problems were most likely to be reported by women aged 55 to 60 years compared with younger and older women. A statistically significant quadratic relation, illustrated in Fig. 1, emerged for the total average symptom score. Women aged 45 to 60 years reported more total symptoms than women younger than age 45 years or older than age 60 years.

With regard to other demographic variables, white women were statistically significantly more likely to report problems on three BCPT symptom scales and the total score than were women of other ethnicities. Women of lower educational level were more likely to be bothered by six of the eight sets of symptoms and by total symptoms than women of higher educational levels. Unmarried women were less bothered by vaginal problems than were married women, but unmarried women reported more problematic symptoms on four BCPT scales.

Women more recently diagnosed with breast cancer were more likely than women diagnosed less recently to be bothered by hot flashes, cognitive problems, and arm problems, but time since cancer diagnosis did not predict other scale scores or the total score. Receipt of chemotherapy predicted symptom experience on the total score and six of eight scales (not bladder control or nausea scores), but type of surgery predicted scores on only one scale (nausea). Finally, current tamoxifen users reported more hot flashes, bladder control problems, and total symptoms but less musculoskeletal pain than nonusers of tamoxifen. Previously statistically significant between-sample differences were no longer statistically significant on three BCPT scales when demographic and treatment-related variables were taken into account, but between-sample differences remained statistically significant on five scales and the total score. However, group differences accounted for no more than 1% of the variance in each symptom scale in the final regression equations.

Table 6. Correlations of the BCPT Symptom Scales with the SF-36 PCS and MCS scores for combined samples 1, 2, and 3 (n = 1983)*

Scales	SF-36 Physical component summary	SF-36 Mental component summary
Hot flash	−0.13	−0.10
Nausea	−0.20	−0.22
Bladder control	−0.21	−0.07
Vaginal problems	−0.01	−0.06
Musculoskeletal pain	−0.54	−0.17
Cognitive problems	−0.21	−0.51
Weight problems	−0.23	−0.29
Arm problems†	−0.22	−0.18
Total score‡	−0.40	−0.36

*Correlations were Pearson's product-moment correlations.

†Correlations for arm problems were computed on samples 2 and 3 (n = 1135).

‡The total score was calculated from the seven scales completed by all three samples.

Discussion

The present report offers a refinement of the original BCPT Symptom Checklist *(11,13)*. Both exploratory and confirmatory factor analyses across four large samples of women previously diagnosed with or at risk for breast cancer revealed eight meaningful factors corresponding to the physical symptom dimensions associated with cancer treatment, chemoprevention, menopause, or normal aging: hot flashes, nausea, bladder control, vaginal problems, musculoskeletal pain, cognitive problems, weight problems, and arm problems.

Internal consistency estimates of reliability exceeding 0.70 for most of the BCPT Symptom Scales are adequate for research

Table 7. Final equations from hierarchical multiple regressions predicting BCPT Symptom Scales with demographic and cancer-related variables across samples 1, 2, and 3*

Predictor variable	Symptom Scale beta value (95% confidence intervel) (*P*)								
	Hot flash	Nausea	Bladder control	Vaginal problems	Musculoskeletal pain	Cognitive problems	Weight problems	Arm problems	Total score
Intercept	−3.84	0.54	−0.50	−1.91	−0.73	0.95	1.18	0.65	−0.51
	(−4.84 to −2.83)	(0.15 to 0.94)	(−1.16 to 0.17)	(−2.87 to −0.95)	(−1.63 to 0.18)	(0.15 to 1.75)	(0.24 to 2.11)	(−0.30 to 1.59)	(−0.99 to −0.03)
	(<.001)	(0.008)	(0.141)	(<.001)	(0.114)	(0.020)	(0.014)	(0.179)	(0.036)
Age (decades)	1.81	−0.06	0.24	0.68	0.68	0.04	0.02	0.03	0.47
	(1.45 to 2.17)	(−0.21 to 0.08)	(0.00 to 0.48)	(0.33 to 1.02)	(0.35 to 1.00)	(−0.24 to 0.33)	(−0.31 to 0.36)	(−0.31 to 0.38)	(0.30 to 0.64)
	(<.001)	(0.382)	(0.047)	(<.001)	(<.001)	(0.762)	(0.900)	(0.861)	(<.001)
$(Age)^2$	−0.17	0.00	−0.01	−0.06	−0.05	−0.01	−0.01	−0.00	−0.04
	(−0.20 to −0.14)	(−0.01 to 0.01)	(−0.03 to 0.01)	(−0.99 to −0.03)	(−0.08 to −.02)	(−0.04 to 0.01)	(−0.04 to 0.02)	(−0.04 to 0.03)	(−0.06 to −0.03)
	(<.001)	(0.714)	(0.305)	(<.001)	(<.001)	(0.383)	(0.409)	(0.770)	(<.001)
Ethnicity	0.14	−0.02	0.06	0.22	0.03	0.17	0.09	−0.07	0.10
(1 = white; 0 = other)	(0.03 to 0.26)	(−0.07 to 0.02)	(−0.02 to 0.13)	(0.11 to 0.33)	(−0.07 to 0.13)	(0.08 to 0.26)	(−0.01 to 0.20)	(−0.17 to 0.04)	(0.04 to 0.15)
	(0.014)	(0.362)	(0.130)	(<.001)	(0.567)	(<.001)	(0.089)	(0.237)	(<.001)
Education	−0.13	−0.04	−0.10	0.01	−0.20	−0.12	−0.13	−0.11	−0.11
(1≥college degree;	(−0.22 to −0.03)	(−0.08 to 0.00)	(−0.16 to −0.03)	(−0.08 to 0.10)	(−0.29 to −.12)	(−0.19 to −0.04)	(−0.22 to −.04)	(−0.20 to −0.02)	(−0.15 to −0.06)
0<college degree)	(0.010)	(0.053)	(0.003)	(0.852)	(<.001)	(0.003)	(0.003)	(0.021)	(<.001)
Married	0.01	−0.05	−0.02	0.42	−0.15	−0.12	−0.11	−0.05	−0.02
(1 = yes; 0 = no)	(−0.08 to 0.11)	(−0.09 to −.01)	(−0.09 to 0.04)	(0.32 to 0.51)	(−0.24 to −.06)	(−0.20 to −0.05)	(−0.20 to −.02)	(−0.14 to 0.04)	(−0.07 to 0.03)
	(0.786)	(0.017)	(0.509)	(<.001)	(0.001)	(0.002)	(0.022)	(0.265)	(0.413)
Time since	−0.05	−0.01	−0.00	0.02	−0.02	−0.03	0.02	−0.04	−0.01
diagnosis (years)	(−0.08 to −0.02)	(−0.02 to 0.00)	(−0.02 to 0.02)	(−0.01 to 0.05)	(−0.05 to 0.00)	(−0.05 to 0.00)	(−0.01 to 0.05)	(−0.06 to −0.01)	(−0.33 to 0.03)
	(0.003)	(0.220)	(0.855)	(0.263)	(0.104)	(0.025)	(0.135)	(0.007)	(0.108)
Chemotherapy	0.29	0.01	0.05	0.38	0.15	0.16	0.27	−0.10	0.18
(1 = yes; 0 = no)	(0.19 to 0.39)	(−0.03 to 0.05)	(−0.01 to 0.12)	(0.28 to 0.48)	(0.06 to 0.24)	(0.08 to 0.24)	(0.18 to 0.37)	(−0.19 to −0.01)	(0.14 to 0.23)
	(<.001)	(0.538)	(0.125)	(<.001)	(0.001)	(<.001)	(<.001)	(0.036)	(<.001)
Surgery	0.02	−0.07	−0.03	0.08	−0.02	−0.04	−0.01	−0.07	−0.01
(1 = lumpectomy;	(−0.08 to 0.12)	(−0.11 to −0.04)	(−0.10 to 0.03)	(−0.01 to 0.17)	(−0.11 to 0.06)	(−0.12 to 0.03)	(−0.10 to 0.08)	(−0.16 to 0.02)	(−0.06 to 0.03)
0 = mastectomy)	(0.684)	(<.001)	(0.302)	(0.077)	(0.623)	(0.250)	(0.825)	(0.118)	(0.591)
Current tamoxifen	0.50	−0.01	0.09	0.00	−0.10	−0.03	0.08	−0.09	0.06
use (1 = yes; 0 = no)	(0.40 to 0.60)	(−0.05 to 0.03)	(0.02 to 0.16)	(−0.10 to 0.10)	(−0.19 to −.01)	(−0.11 to 0.05)	(−0.01 to 0.18)	(−0.19 to 0.01)	(0.01 to 0.11)
	(<.001)	(0.495)	(0.009)	(0.984)	(0.031)	(0.532)	(0.081)	(0.084)	(0.015)
Sample 3 = 1;	0.04	0.04	−0.21	−0.27	−0.10	−0.12	−0.02		−0.09
Other samples = 0	(−0.10 to 0.18)	(−0.02 to 0.09)	(−0.31 to −0.12)	(−0.40 to −0.14)	(−0.22 to 0.03)	(−0.23 to −0.01)	(−0.15 to 0.11)		(−0.16 to −0.03)
	(0.583)	(0.108)	(<.001)	(<.001)	(0.134)	(0.040)	(0.751)		(0.005)
Sample 2 = 1;	0.03	0.02	−0.03	0.02	−0.20	−0.00	−0.10	0.34	−0.04
Other samples = 0	(−0.12 to 0.18)	(−0.04 to 0.08)	(−0.13 to 0.07)	(−0.13 to 0.16)	`(−0.34 to −.07)	(−0.12 to 0.12)	(−0.24 to 0.04)	(0.16 to 0.51)	(−0.12 to 0.03)
	(0.707)	(0.461)	(0.534)	(0.815)	(0.004)	(0.993)	(0.150)	(<.001)	(0.216)
R^2 Δ demographic	0.07	0.01	0.04	0.06	0.03	0.03	0.03	0.01	0.03
R^2 Δ cancer vars.	0.08	0.01	0.01	0.04	0.01	0.01	0.02	0.02	0.03
R^2 Δ sample	0.00	0.00	0.01	0.01	0.01	0.00	0.00	0.01	0.01
Total R^2	0.15	0.02	0.06	0.11	0.05	0.04	0.05	0.04	0.07
F value (df) for	31.89	4.53	10.64	21.20	8.57	7.00	9.12	4.41	13.03
all predictors	(11; 1947)	(11; 1943)	(11; 1944)	(11; 1943)	(11; 1944)	(11; 1943)	(11; 1945)	(10; 1092)	(11; 1947)

*Entries for single predictors are beta weights (and confidence intervals) and *P* values in the final regression equations. Change in R^2 is shown for the entry of (a) demographic variables (i.e., age, age^2, ethnicity, education, marital status) as a set, (b) cancer-related variables (i.e., time since diagnosis, chemotherapy receipt, surgery type, and current tamoxifen use) as a set, and (c) indicators for sample. In the regression analysis for the Arm Problems score, only samples 2 and 3 were used and the beta weight is for the comparison of those two samples. All F values for the final regression equations were significant at *P*<.0001.

purposes *(33)*, although the internal consistency estimates were somewhat lower for the nausea and weight problems scales, which might require further refinement. The scales were modestly intercorrelated, suggesting that women can distinguish among various symptom dimensions. On average, women reported being "not at all" to "slightly" bothered by the symptoms, with mean scores somewhat higher on scales reflecting hot flashes, pain, and weight problems than on other scales. In interpreting the relatively low mean scores on the scales, it is important to note that women actually receiving treatment for breast cancer are not represented in our samples (although women in sample 3 had recently completed medical treatments for breast cancer). We would expect that breast cancer patients receiving treatment would report a greater number of problematic symptoms and that, specifically, women undergoing chemotherapy would report greater problems associated with hot flashes, nausea, vaginal dryness, and cognitive problems than were reported by women in our samples.

Women in the sample who recently had completed medical treatments for breast cancer reported statistically significantly more problematic hot flashes than did women in the other samples; however, their scores on other symptom scales, in general, were not increased relative to those of the other samples of women diagnosed with breast cancer an average of 3 years (sample 1) or 6 years (sample 2) previously. Moreover, in keeping with our hypothesis, scores on the BCPT Symptom Scales and the total score generally were lower in women at risk for breast cancer (sample 4) than scores in women diagnosed with breast cancer. However, it should be noted that women in sample 4 also were relatively young compared with the women in the other samples. Overall, between-sample differences in the BCPT Symptom Scales were modest, accounting for no more than 1%

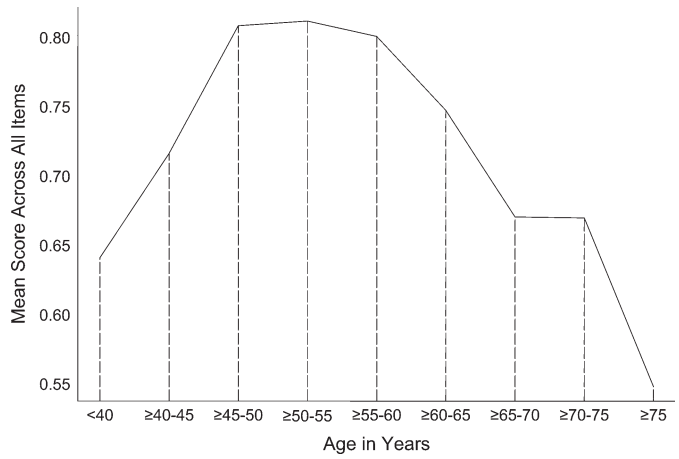

Fig. 1. Quadratic relation of mean total symptoms score with age among women previously diagnosed with or at high risk for breast cancer. Mean score across all items on the BCPT Symptom Scales (excluding Arm Problems) is on the vertical axis, and age group is on the horizontal axis.

of the variance in symptom scale scores once demographic and cancer-related variables were taken into account.

The BCPT Symptom Scales offer information that is distinct from a widely used measure of HRQOL, the SF-36, as indicated by correlations between the symptom scales and the SF-36 scales lower than r = .30 for most scales. The strongest correlations were obtained between the BCPT Musculoskeletal Pain scale and the SF-36 PCS, which contains items to assess pain, and between the BCPT Cognitive Problems Scale and the SF-36 MCS, reflecting their common psychologic content. Thus, the BCPT Symptom Scales demonstrated good discriminant validity relative to the more general HRQOL measure.

We expected that demographic and cancer-related variables would be related to scores on the BCPT Symptom Scales. However, most of those variables were not strong predictors of the BCPT Symptom Scale scores. Demographic variables alone accounted for between 1% and 7% of the total variance in symptom scores, with an additional 1% to 8% of the variance accounted for by cancer-related variables. The most consistent demographic predictor was education level: women who had completed college were statistically significantly less likely to report problematic symptoms on six of eight scales and total symptoms than women who had not completed college. Education is a frequently used indicator of socioeconomic status, a variable that has consistent associations with morbidity and mortality across the lifespan *(34,35)*. Lower socioeconomic status environments are associated with fewer tangible and psychosocial resources, which might confer vulnerability to or deplete women's reserve capacity to manage physical symptoms, particularly in the context of having been diagnosed with breast cancer *(35)*. We should note, however, that women in our samples were relatively highly educated, and further investigation of the link between education and self-reported physical symptoms is warranted.

In addition to having higher education, being married was also associated with fewer symptoms, perhaps suggesting that supportive relationships can aid women in managing symptoms. The exception was that vaginal problems were more bothersome for married women than for unmarried women, who perhaps had less active sexual relationships. We had also hypothesized that older women would report more physical symptoms than younger women, and this hypothesis received support on the scales reflecting symptoms associated with normal aging *(11,20)*: Hot Flashes, Bladder Control, Vaginal Problems, and Musculoskeletal Pain. As suggested in other research *(11,32)*, curvilinear relations with age emerged for three scales (i.e., Hot Flashes, Vaginal Problems, Musculoskeletal Pain) and the total score, suggesting on the total score, for example, that women aged 45 to 60 years may be more vulnerable to symptoms than older or younger women.

With regard to cancer-related predictors, having undergone chemotherapy was the most consistent predictor of bothersome symptoms in that it was associated with greater reporting of hot flashes, vaginal problems, pain, cognitive problems, weight concerns, and total symptoms. It is notable that these associations emerged in samples of women who had completed chemotherapy—some as many as several years previously. Furthermore, receipt of chemotherapy was a stronger predictor of symptoms than was time elapsed since diagnosis. In sum, the sets of demographic and cancer-related variables together accounted for 2% (for the nausea score) to 15% (for the hot flash score) of the variance in the BCPT Symptom Scales, suggesting that additional biological, behavioral, psychosocial, and environmental factors contribute to physical symptom experience.

The BCPT Symptom Scales developed in this study may be of use to clinicians interested in monitoring side effect profiles of their patients, researchers conducting clinical trials of therapies for breast cancer or cancer prevention, and women seeking information on what to expect from breast cancer treatment or chemoprevention. However, our study does not provide data on women currently undergoing medical treatments for breast cancer or on women with advanced disease, and further investigation of the psychometric properties and validity of the BCPT Symptom Scales is warranted. Furthermore, the BCPT Symptom Scales do not capture all expected side effects of breast cancer treatments or chemoprevention, such as fatigue and breast-specific pain. Other instruments are available to assess fatigue *(36,37)* and specific effects of breast cancer surgery, such as arm function, breast-specific pain, and changes in appearance *(38,39)*. Consequently, researchers might want to add items or scales to reflect the symptom dimensions of particular relevance to their research. In addition, the clinical relevance of specific scale scores requires study. However, the extraction of coherent symptom dimensions across the four samples of women and their logically meaningful associations with demographic and cancer-related variables provide evidence that the BCPT Symptom Scales offer a valuable refinement of the original instrument.

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Notes

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