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HEALTH-RELATED QUALITY OF LIFE IN WOMEN PREVIOUSLY TREATED FOR EARLY-STAGE BREAST CANCER:

FOR THE WOMEN'S HEALTHY EATING AND LIVING (WHEL) STUDY GROUP

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SUMMARY

This study describes health-related quality of life (HRQOL) in women previously treated for early stage breast cancer relative to general population and breast cancer norms. It also identifies correlates and multivariate predictors of physical and mental HRQOL. 2582 women who were up to four years post-treatment for early stage breast cancer completed the RAND-36 Health Survey and reported personal and cancer-related information. Participants reported generally high HRQOL that was comparable to norms for women in the general population and other women with breast cancer. In multivariate analyses, better physical HRQOL was associated with fewer psychological symptoms, lower body mass index, better sleep quality, and more physical activity. Better mental HRQOL was associated with better sleep quality, fewer life events, less pain, and fewer gastrointestinal symptoms. Interventions targeting psychosocial symptoms, weight reduction, physical activity, sleep hygiene, and pain could result in improved HRQOL in these women.

INTRODUCTION

Health-related Quality of Life (HRQOL) refers to a person's subjective assessment of physical, emotional, social, and cognitive functioning in the context of disease symptoms and treatment (Bottomley and Therasse, 2002). There is a need to better understand HRQOL throughout the course of breast cancer (Rowland and Massie, 1998) and to update that knowledge as treatments evolve (Fallowfield, 2002). HRQOL has only recently been included as an outcomes measure in phase III breast cancer clinical trials (Bottomley *et al.*, 2003) even though HRQOL is seen as a good prognostic indicator in a variety of cancers,

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including breast cancer (Coates and Gebski, 1996). However, little is known about predictors of HRQOL in breast cancer patients.

The diagnosis of breast cancer itself can have a complex impact on HRQOL (Rowland and Massie, 1998). In addition, breast cancer treatment can cause adverse effects and is intensive, resulting in significant demands on psychosocial resources. The likelihood of surviving this disease has increased significantly with multimodal treatment (Early Breast Cancer Trialists' Collaborative Group, 1992). However, patients must endure longer periods of treatment that have varying impact on HRQOL, depending on the type of treatment received, stage of disease, and other patient characteristics (Ganz *et al.*, 1998a; Meyerowitz *et al.*, 1983). Recent studies of HRQOL in breast cancer have shown that, as a group, these women report HRQOL levels similar to demographically matched comparison groups (Bower *et al.*, 2000). Nonetheless, 20–30% of women with breast cancer report ongoing psychosocial distress due to difficulties in coping with this disease (Keller, 1998).

Though detailed data on HRQOL in large studies of breast cancer survivors are still relatively limited, poorer HRQOL has been associated with various patient characteristics. Demographic correlates of worse HRQOL include younger age (Bower et al., 2000; Parker et al., 2003), lower socioeconomic status (Bower et al., 2000; King et al., 2000), non-Caucasian ethnicity (Gotay et al., 2002; Payne et al., 2003), and not having a primary relationship (Bower et al., 2000; Parker et al., 2003). Health behavior correlates include current smoking (McBride et al., 2000), poorer diet (Maunsell et al., 2002; Rock and Demark-Wahnefried, 2002), and decreased physical activity (Kolden et al., 2002; Pinto et al., 2002). Cancer-specific correlates include later cancer stage (Rowland and Massie, 1998), treatment (Bottomley and Therasse, 2002; Payne et al., 2003), and less time since diagnosis (Cimprich et al., 2002; Kessler, 2002). Psychosocial correlates include mood disturbance/ depression (Bower et al., 2000; Broeckel et al., 1998; Shapiro et al., 2001), anxiety (Shapiro et al., 2001), anger/hostility (Shapiro et al., 2001), decreased social support (Bower et al., 2000; Northouse et al., 2002; Parker et al., 2003), disturbed sleep (Bower et al., 2000; Fortner et al., 2002), more life events (Kornblith et al., 2001), less negative emotional expressiveness (Classen et al., 1996), and less optimism (Northouse et al., 1999). In addition, overweight (Rock, Demark-Wahnefried, 2002), more physical symptoms (Bower et al., 2000), and more pain (Bower et al., 2000; Fortner et al., 2002) have been linked to worse HRQOL.

The purpose of this paper is to describe HRQOL and factors associated with it in women treated for early stage breast cancer, relative to population norms and other studies of women with breast cancer. Based on findings cited above, we hypothesize that poorer Physical HRQOL will be associated with less time since diagnosis, later stage, overweight, poorer psychosocial functioning, and unhealthy behaviors. We hypothesize that poorer Mental HRQOL will be associated with younger age, lower education, not having a primary relationship, unhealthy behaviors, less time since diagnosis, more life events, poor sleep, and more physical symptoms.

METHODS

Participants

3088 women treated for early stage breast cancer were recruited to participate in the Women's Healthy Eating and Living (WHEL) Study from seven clinical sites in California, Oregon, Arizona, and Texas. A subset of 2582 women who had complete data on all variables of interest was used for the current analyses. The study protocol has been described elsewhere (Pierce *et al.*, 2002). Briefly, recruitment strategies included: letters to women identified from tumor registries; referrals from local oncologists; and community outreach (distributing study brochures; presentations to local breast cancer support groups and events). Additionally, a brief description of the study and an invitation to enroll were presented in local mass media (newspaper, radio, television stations) with a toll-free number for contacting the study.

Measurement

Each participant was asked, at baseline, to complete a series of questionnaires assessing personal characteristics, including habits and health behaviors. Demographic data were collected by a telephone screening interview and study forms. All questionnaires were completed either before or at a baseline clinic visit, at which the women were weighed and measured using standard procedures. Additional details have been described elsewhere (Pierce *et al.*, 2002).

Health related quality of life and Psychosocial functioning

The 147-item Thoughts and Feelings Questionnaire adapted from the Women's Health Initiative was used to assess HRQOL and psychosocial functioning (Matthews et al., 1997). This assesses social support (9 item MOS Social Support; a=0.93 (Sherbourne and Stewart, 1991)), social integration and life events (5 and 11 items, respectively, modified from Alameda County Study (Berkman and Syme, 1979)), social strain (4 items from national surveys; a=0.71 (Antonucci et al., 1989)), optimism (6 items from the Life Orientation Test-Revised; a=0.79 (Scheier et al., 1994)), negative emotional expressiveness (NEE) (7 items; α =0.64 (King and Emmons, 1990)), hostility (13-item Cook-Medley Cynicism sub-scale; a=0.74 (Barefoot et al., 1989)), HRQOL (RAND-36 (Ware and Sherbourne, 1992), see below), symptoms (34 items from the PEPI Trial and national surveys (Matthews et al., 1994), see below), depressive symptoms (8 item Center for Epidemiologic Studies-Depression short-form (CES-D-sf); a=0.77 (Hann *et al.*, 1999)), and sleep (10 items selected by sleep researchers; a=0.68 (Matthews et al., 1997)). Because response bias can influence self-reported data, a 10-item version of the Marlowe-Crowne Social Desirability Scale (MCSDS) was included to determine if response bias affected these data (Fischer and Fick, 1993).

Health-related quality of life assessment

Participants completed the most widely used short form of the Medical Outcomes Study (MOS) Functioning and Well-being Profile (Stewart and Ware, 1992): the RAND-36-Item Health Survey. This measures aspects of health relevant to everyone's functional status and

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well-being that are not age, disease, or treatment specific (Ware *et al.*, 2000). It has been used for assessment and evaluation of various populations (Stewart and Ware, 1992; Wyatt *et al.*, 1998) including women with breast cancer (Ganz *et al.*, 1995; Goodwin *et al.*, 2003). Responses are summarized into four mental (mental health index, vitality, role limitations due to emotional problems, social functioning) and four physical (physical functioning, general health perceptions, bodily pain, role limitations due to physical health problems) subscales. These dimensions can be consolidated into separate mental and physical HRQOL summary scales (Ware *et al.*, 2000).

Subscale scores range from 0 to 100, with higher scores indicating better health. General Health, Mental Health Index, and Vitality are 'bipolar' subscales. If no limitations are reported on these bipolar subscales, scores will be around the midpoint of 50. When positive states are endorsed, scores will exceed 50; when limitations are endorsed, scores will fall below 50. While the current study was sufficiently powered to detect two-point differences, five-point differences are considered clinically meaningful. The RAND-36 subscales have been shown to be reliable (Cronbach's α =0.75 to 0.91) and to have adequate-to-substantial construct validity in a variety of medically ill populations (Ware *et al.*, 2000).

We were interested in comparing RAND-36 scores for these women against norms and other women with breast cancer. To this end, we used RAND-36 normative data for women in the general population (Ware *et al.*, 2000) and selected two recent well-designed studies that used the RAND-36 (see Table 1). (Ganz *et al.*, 1998a, b).

Symptoms

The 34-item symptom inventory assesses the occurrence and severity of symptoms, rated from 0 ('No Occurrence') to 3 ('Severe Symptom') (Matthews *et al.*, 1994). Exploratory factorial analysis was used to detect patterns of symptoms and to reduce the number of variables necessary to describe them. Using orthogonal rotation, this analysis suggested a five-factor solution (overall Cronbach's a=0.79), which was both statistically and clinically relevant. The resulting five symptom groups have been named: Psychological (difficulty concentrating, forgetful, mood swings, restless/fidgety, clumsy; a=0.75), Pain (joint pain/stiffness, aches/pains, low back pain, neck pain; a=0.74), Gastrointestinal (upset stomach/pain/discomfort, nausea, diarrhea; a=0.63), Vasomotor (hot flashes, night sweats; a=0.82), and Genitourinary (vaginal/genital irritation/itch, vaginal/genital discharge, pain/burning urination; a=0.51).

Statistical analysis

Independent *t*-tests were used to compare differences between mean RAND-36 scores of participants to norms. Pearson correlation analysis was conducted to examine associations between participant characteristics and the Physical and Mental Health summary scales. We used the criterion for meaningfulness of association suggested by authors of the MOS: Pearson's $t \ge 0.23$ (5% of variance) (Stewart and Ware, 1992). Multiple linear regression was used to model associations between each RAND-36 summary scale with demographic, behavioral, and other factors. Log transformation of alcohol data was conducted to approximate a Gaussian distribution. Because of the sample size, there is a likelihood of

observing clinically meaningless associations between the independent (IV) and dependent (DV) variables in the multiple regression models. Therefore, we considered an IV to contribute meaningfully only when p 0.001. All statistical analyses were performed using SPSS 10.1 (Chicago, 2001).

RESULTS

Participant characteristics

Participants averaged 53 years of age (range=28–74) and were highly educated: more than half graduated from college and 88% had some post-high school education. Mean BMI was 27.4 kg/m²; thus, the average participant would be considered overweight (NIH, 1998). Eighty-five percent of the women were Caucasian, 5% Hispanic, 4% African-American, 4% Asian/Pacific Islander, which is representative of the general population of women with early stage breast cancer. Seventy-one percent of the women were married or in a significant relationship.

Just under 40% of participants were diagnosed with Stage 1 (\geq 1 cm), 56% with Stage II, and 5% with Stage IIIA breast cancer, averaging 2 years since diagnosis at study entry. Sixty-one percent of participants had tumors classified as estrogen- and progesterone-receptor positive; 60% were using tamoxifen at study entry. Approximately 45% reported a history of using hormone replacement therapy prior to their breast cancer diagnosis.

Only 5% reported being current smokers (mean=6.5 pack years); half had never smoked. Participants averaged 841 metabolic equivalents of physical activity per week; just over 25% met physical activity guidelines for healthy living at baseline. When evaluating dietary intake, we observed that 32% (\pm 3.2) of the women met all three NCI dietary recommendations (see Table 2, footnote 'a'), 30% (\pm 3.2) met two, 24% (\pm 3.4) met one, and 14%(\pm 3.6) met none.

Because a number of women did not have complete data for all variables, we wanted to ensure that women with and without complete data did not differ on the variables of interest. We ran separate ANOVAs for each variable in Table 2; no meaningful differences were found.

Health-related quality of life

Table 1 presents mean RAND-36 HRQOL scores for our participants, norms, and the two breast cancer comparison studies. On the three bipolar subscales, mean scores for participants ranged from no limitations for Vitality (58.8±20.9) to positive states for General (71.5 18.7) and Mental Health (76.7±15.0). On the five other subscales, scores were quite high across all women, ranging from 71 for role limitations—physical to 87 for Social Functioning.

By and large, participants reported HRQOL levels similar to general population norms for US women. For 5 of 8 subscales, participants appeared to report greater health than norms. However, these scores were significantly different (P<0.05) only for Physical Functioning, Mental Health, and Social Functioning. In addition, participants scored significantly lower

than norms for role limitations—physical. Yet clinically meaningful differences (± 5 points) were observed only for role limitations—physical (6.7 points worse) and Social Functioning (5.2 points healthier). When compared with the other two breast cancer studies, meaningful differences emerged only for role limitations—emotional (our participants 5.1 points healthier).

Pearson's correlations

Correlations between MCSDS scores and all HRQOL and psychosocial variables were low (r < 0.18), suggesting that, overall, socially desirable responding was not having a meaningful impact on the self-report of HRQOL and psychosocial functioning.

Table 2 shows correlations for the RAND-36 Physical and Mental Health scales vs. participant variables. Correlations meeting or exceeding the $r \ge 0.23$ criterion for meaningfulness are asterisked. In descending order of correlation, better Physical Health was associated with less pain, fewer psychological symptoms, fewer gastrointestinal symptoms, less insomnia, lower BMI, fewer depressive symptoms, less social strain, and more physical activity. Better Mental Health was associated with fewer psychological symptoms, fewer depressive symptoms, fewer depressive symptoms, less social strain, more social support, less pain, less insomnia, fewer life events, fewer gastrointestinal symptoms, less ambivalence over NEE, and less hostility.

Multivariate analysis

Tables 3a and 3b show results of the multivariate analysis using RAND-36 Physical and Mental Health summary scales as DVs and the variables asterisked in Table 2 as IVs. Most of the rest of the variables were included as covariates; however, some had obvious overlap with either Physical or Mental Health. Pain, vasomotor, genitourinary, and gastrointestinal symptoms were excluded when modeling Physical Health. NEE, ambivalence over NEE, depressive symptoms, hostility, optimism, social strain, social support, and psychological symptoms were excluded when modeling Mental Health.

For Physical Health (Table 3a), although the initial covariates explained only 16% of the variance observed, by adding in the variables of interest the percentage doubled (R^2 =0.32, F=45.184, p<0.001). In order of strength of relationship with Physical Health, psychological symptoms, BMI, poor sleep quality, and physical activity met the p 0.001 criterion. Depressive symptoms (p=0.011), and social strain (p=0.027) fell short of the p 0.001 criterion.

For Mental Health (Table 3b), the initial covariates explained 15% of the observed variance and the variables of interest explained an additional 15% of variance (R^2 =0.30, F=50.690, p<0.001). In order of strength of relationship with Mental Health, poor sleep quality, life events, pain symptoms, and gastrointestinal symptoms met the p 0.001 criterion.

DISCUSSION

Understanding HRQOL in women with breast cancer has become increasingly important. HRQOL assessment is essential to identify women in need of psychosocial interventions and

also as a key criterion in evaluating treatments. In the current study, we described HRQOL in a large sample of women previously treated for early stage breast cancer. The data were compared with norms for the general population and other women with this disease. In addition, we determined which patient characteristics are meaningfully associated with physical and mental HRQOL.

Participants were highly educated, predominantly Caucasian, and somewhat overweight similar to breast cancer patients from the Ganz *et al.* studies (Ganz *et al.*, 1998a, b). Overall, participants reported relatively high levels of HRQOL. This replicates previous findings that HRQOL in women with breast cancer is similar to that of the general population (Bower *et al.*, 2000; Ganz *et al.*, 1998a) and specifically to MOS normative data for US women (Ware *et al.*, 2000). Although HRQOL was high overall, a large group of women reported significant levels of distress (e.g., 17% had CES-D-sf scores \geq 0.06, indicating the likelihood of a mood disorder). This is consistent with previous findings (Keller, 1998).

Meaningful differences emerged between our participants and general population norms on two RAND-36 subscales: our participants reported more role limitations due to physical problems and better social functioning. Women in our study averaged two years since diagnosis, whereas women in the two comparison breast cancer studies averaged three years. Elsewhere, HRQOL has been shown to improve with greater time since diagnosis. Thus, compared with the breast cancer groups, our participants reported statistically significant (but not meaningful) differences in role limitations due to physical problems; our cohort did have meaningful differences on this variable when compared with population norms. Regarding social functioning, scores for our participants were nearly identical to those for the two breast cancer comparison groups. Social functioning differences between those comparison groups and norms fell just short of meaningfulness. Thus, our data replicate previous findings that, overall, women post-treatment for breast cancer report better social functioning than women in the general population.

Only one meaningful difference was observed between the current study and one of the breast cancer comparison groups: our participants reported fewer role limitations due to emotional problems (5.1 points less). One possible explanation is that our participants were approximately 2 years younger on average and age has often shown a positive relationship with emotional functioning in women with breast cancer. However, the 5.1 point difference barely exceeds the criterion for meaningfulness; replication is required before much can be made of it. Most important, however, is that when viewed at the level of the summary Health and Physical variables, no differences emerge for the current study vs population norms or the other breast cancer studies. In general, women treated for breast cancer show similar levels of functioning across studies that shows little difference from that of women in the general US population.

We were also interested in identifying correlates of HRQOL. In our sample of women breast cancer survivors, cancer-related, demographic, and health behavior variables (except physical activity) are not important HRQOL correlates. The most consistent associations with both physical and mental HRQOL were for psychosocial variables and physical symptoms.

When the IVs were allowed to compete in multivariate analysis, we observed that poorer Physical HRQOL was associated with poorer psychosocial functioning, greater obesity, worse sleep quality, and less physical activity. As in the univariate analyses, the hypothesized relationships between breast cancer variables and Physical HRQOL did not emerge. For Mental HRQOL, worse functioning was associated with poorer sleep quality, more life events, and more pain and gastrointestinal symptoms. Thus, hypothesized relationships for Mental HRQOL vs demographic, health behavior, and breast cancer variables did not emerge when all variables of interest were in the model.

Of those variables which did explain meaningful portions of variance in HRQOL, it is clinically relevant that several variables are related to health behaviors that are responsive to psychosocial intervention. While we cannot assume causality, interventions targeting psychosocial symptoms, weight reduction, physical activity, sleep hygiene, and pain could result in HRQOL improvements in women with breast cancer.

Limitations

This study relied on a predominantly Caucasian, highly educated, higher SES volunteer sample. Results may not be generalizable to less educated, lower SES, non-volunteer breast cancer survivors of varied ethnic or racial backgrounds. Because HRQOL assessment is best achieved through patient self-report, we relied on standard pencil-and-paper scales to measure this construct. Self-report instruments can be influenced by response bias, thus reducing accuracy. However, the Marlowe-Crowne Social Desirability scale was not meaningfully related with HRQOL in this study. This suggests that this form of response bias did not meaningfully affect HRQOL assessment overall. We relied on the RAND-36, the most frequently used measure of HRQOL. However, this is a generic instrument, not one that is specific to breast cancer. While this instrument has been used frequently to assess HRQOL in breast cancer patients, it may lack specificity in certain domains. Finally, because the design is cross-sectional, the directionality of relationships between HRQOL and any of the IVs cannot be assumed.

Summary and conclusions

Poorer physical and mental HRQOL is associated with a variety of patient characteristics, many of which may be amenable to clinical intervention. Interventions targeting psychosocial factors, physical symptoms, and health behavior-related variables could result in improved HRQOL in these women.

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References

Antonucci, T., Kahn, R., Akiyama, H. Psychosocial factors and the response to cancer symptoms. In: Yancik, R., Yates, J., editors. Cancer in the Elderly: Approaches to Early Detection and Treatment. New York: Springer; 1989.

- Barefoot JC, Dodge KA, Peterson BL, Dahlstrom WG, Williams RB Jr. The Cook–Medley hostility scale: Item content and ability to predict survival. Psychosom Med. 1989; 51:46–57. [PubMed: 2928460]
- Berkman LF, Syme SL. Social networks, host resistance, and mortality: A nine-year follow-up study of Alameda County residents. Am J Epidemiol. 1979; 109:186–204. [PubMed: 425958]
- Bottomley A, Therasse P. Quality of life in patients undergoing systemic therapy for advanced breast cancer. Lancet Oncol. 2002; 3:620–628. [PubMed: 12372724]
- Bottomley A, Vanvoorden V, Flechtner H, Therasse P. The challenges and achievements involved in implementing Quality of Life research in cancer clinical trials. Eur J Cancer. 2003; 39:275–285. [PubMed: 12565977]
- Bower JE, Ganz PA, Desmond KA, Rowland JH, Meyerowitz BE, Belin TR. Fatigue in breast cancer survivors: Occurrence, correlates, and impact on quality of life. J Clin Oncol. 2000; 18:743–753. [PubMed: 10673515]
- Broeckel JA, Jacobsen PB, Horton J, Balducci L, Lyman GH. Characteristics and correlates of fatigue after adjuvant chemotherapy for breast cancer. J Clin Oncol. 1998; 16:1689–1696. [PubMed: 9586880]
- Cimprich B, Ronis DL, Martinez-Ramos G. Age at diagnosis and quality of life in breast cancer survivors. Cancer Pract. 2002; 10:85–93. [PubMed: 11903273]
- Classen C, Koopman C, Angell K, Spiegel D. Coping styles associated with psychological adjustment to advanced breast cancer. Health Psychol. 1996; 15:434–437. [PubMed: 8973923]
- Coates A, Gebski V. On the receiving end. VI. Which dimensions of quality-of-life scores carry prognostic information? Cancer Treat Rev. 1996; 22(Suppl A):63–67. [PubMed: 8625351]
- Early Breast Cancer Trialists' Collaborative Group. Systemic treatment of early breast cancer by hormonal, cytotoxic, or immune therapy. 133 randomised trials involving 31,000 recurrences and 24,000 deaths among 75,000 women. Early Breast Cancer Trialists' Collaborative Group. Lancet. 1992; 339:71–85. [PubMed: 1345869]
- Fallowfield L. Quality of life: A new perspective for cancer patients. Nat Rev Cancer. 2002; 2:873– 879. [PubMed: 12415257]
- Fischer DG, Fick C. Measuring social desirability: Short forms of the Marlowe–Crowne Social Desirability Scale. Educ Psychol Meas. 1993; 53:417–424.
- Fortner BV, Stepanski EJ, Wang SC, Kasprowicz S, Durrence HH. Sleep and quality of life in breast cancer patients. J Pain Symptom Manage. 2002; 24:471–480. [PubMed: 12547047]
- Ganz PA, Day R, Ware JE Jr, Redmond C, Fisher B. Base-line quality-of-life assessment in the National Surgical Adjuvant Breast and Bowel Project Breast Cancer Prevention Trial. J Natl Cancer Inst. 1995; 87:1372–1382. [PubMed: 7658498]
- Ganz PA, Rowland JH, Desmond K, Meyerowitz BE, Wyatt GE. Life after breast cancer: Understanding women's health-related quality of life and sexual functioning. J Clin Oncol. 1998a; 16:501–514. [PubMed: 9469334]
- Ganz PA, Rowland JH, Meyerowitz BE, Desmond KA. Impact of different adjuvant therapy strategies on quality of life in breast cancer survivors. Recent Results Cancer Res. 1998b; 152:396–411. [PubMed: 9928575]
- Goodwin PJ, Black JT, Bordeleau LJ, Ganz PA. Health-related quality-of-life measurement in randomized clinical trials in breast cancer-taking stock. J Natl Cancer Inst. 2003; 95:263–281. [PubMed: 12591983]
- Gotay CC, Holup JL, Pagano I. Ethnic differences in quality of life among early breast and prostate cancer survivors. Psychooncology. 2002; 11:103–113. [PubMed: 11921326]
- Hann D, Winter K, Jacobsen P. Measurement of depressive symptoms in cancer patients: Evaluation of the Center for Epidemiological Studies Depression Scale (CES-D). J Psychosom Res. 1999; 46:437–443. [PubMed: 10404478]
- Keller M. Psychosocial care of breast cancer patients. Anticancer Res. 1998; 18:2257–2259. [PubMed: 9703797]
- Kessler TA. Contextual variables, emotional state, and current and expected quality of life in breast cancer survivors. Oncol Nurs Forum. 2002; 29:1109–1116. [PubMed: 12183759]

- King LA, Emmons RA. Conflict over emotional expression: Psychological and physical correlates. J Pers Soc Psychol. 1990; 58:864–877. [PubMed: 2348373]
- King MT, Kenny P, Shiell A, Hall J, Boyages J. Quality of life three months and one year after first treatment for early stage breast cancer: Influence of treatment and patient characteristics. Qual Life Res. 2000; 9:789–800. [PubMed: 11297021]
- Kolden GG, Strauman TJ, Ward A, Kuta J, Woods TE, Schneider KL, Heerey E, Sanborn L, Burt C, Millbrandt L, Kalin NH, Stewart JA, Mullen B. A pilot study of group exercise training (GET) for women with primary breast cancer: Feasibility and health benefits. Psycho-Oncology. 2002; 11:447–456. [PubMed: 12228878]
- Kornblith AB, Herndon JE, Zuckerman E, Viscoli CM, Horwitz RI, Cooper MR, Harris L, Tkaczuk KH, Perry MC, Budman D, Norton LC, Holland J. Social support as a buffer to the psychological impact of stressful life events in women with breast cancer. Cancer. 2001; 91:443–454. [PubMed: 11180093]
- Matthews KA, Shumaker SA, Bowen DJ, Langer RD, Hunt JR, Kaplan RM, Klesges RC, Ritenbaugh C. Women's health initiative. Why now? What is it? What's new? Am Psychol. 1997; 52:101–116. [PubMed: 9104085]
- Matthews KA, Wing RR, Kuller LH, Meilahn EN, Plantinga P. Influence of the perimenopause on cardiovascular risk factors and symptoms of middle-aged healthy women. Arch Intern Med. 1994; 154:2349–2355. [PubMed: 7944857]
- Maunsell E, Drolet M, Brisson J, Robert J, Deschenes L. Dietary change after breast cancer: Extent, predictors, and relation with psychological distress. J Clin Oncol. 2002; 20:1017–1025. [PubMed: 11844825]
- McBride CM, Clipp E, Peterson BL, Lipkus IM, Demark-Wahnefried W. Psychological impact of diagnosis and risk reduction among cancer survivors. Psycho-Oncology. 2000; 9:418–427. [PubMed: 11038480]
- Meyerowitz BE, Watkins IK, Sparks FC. Psychosocial implications of adjuvant chemotherapy. A twoyear follow-up. Cancer. 1983; 52:1541–1545. [PubMed: 6616414]
- NIH. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: The evidence report. 1998. NIH Publ. No. 98-4083
- Northouse LL, Caffey M, Deichelbohrer L, Schmidt L, Guziatek-Trojniak L, West S, Kershaw T, Mood D. The quality of life of African American women with breast cancer. Res Nurs Health. 1999; 22:449–460. [PubMed: 10630287]
- Northouse LL, Mood D, Kershaw T, Schafenacker A, Mellon S, Walker J, Galvin E, Decker V. Quality of life of women with recurrent breast cancer and their family members. J Clin Oncol. 2002; 20:4050–4064. [PubMed: 12351603]
- Parker PA, Baile WF, DeMoor C, Cohen L. Psychosocial and demographic predictors of quality of life in a large sample of cancer patients. Psycho-Oncology. 2003; 12:183–193. [PubMed: 12619150]
- Payne R, Medina E, Hampton JW. Quality of life concerns in patients with breast cancer: Evidence for disparity of outcomes and experiences in pain management and palliative care among African-American women. Cancer. 2003; 97:311–317. [PubMed: 12491494]
- Pierce JP, Faerber S, Wright FA, Rock CL, Newman V, Flatt SW, Kealey S, Jones VE, Caan BJ, Gold EB, Haan M, Hollenbach KA, Jones L, Marshall JR, Ritenbaugh C, Stefanick ML, Thomson C, Wasserman L, Natarajan L, Thomas RG, Gilpin EA. A randomized trial of the effect of a plant-based dietary pattern on additional breast cancer events and survival: The women's healthy eating and living (WHEL) study. Control Clin Trials. 2002; 23:728–756. [PubMed: 12505249]
- Pinto BM, Trunzo JJ, Reiss P, Shiu SY. Exercise participation after diagnosis of breast cancer: Trends and effects on mood and quality of life. Psycho-Oncology. 2002; 11:389–400. [PubMed: 12228872]
- Rock CL, Demark-Wahnefried W. Nutrition and survival after the diagnosis of breast cancer: A review of the evidence. J Clin Oncol. 2002; 20:3302–3316. [PubMed: 12149305]
- Rowland, JH., Massie, MJ. Breast Cancer. In: Holland, JC., editor. Psycho-oncology. Oxford University Press; New York: 1998. p. 380-401.

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- Scheier MF, Carver CS, Bridges MW. Distinguishing optimism from neuroticism (and trait anxiety, self-mastery, and self-esteem): A reevaluation of the Life Orientation Test. J Pers Soc Psychol. 1994; 67:1063–1078. [PubMed: 7815302]
- Shapiro SL, Lopez AM, Schwartz GE, Bootzin R, Figueredo AJ, Braden CJ, Kurker SF. Quality of life and breast cancer: Relationship to psychosocial variables. J Clin Psychol. 2001; 57:501–519. [PubMed: 11255204]
- Sherbourne CD, Stewart AL. The MOS social support survey. Soc Sci Med. 1991; 32:705–714. [PubMed: 2035047]
- Stewart, AL., Ware, JE. Measuring Functioning and Well-Being: The Medical Outcomes Study Approach. Duke University Press; Durham, NC: 1992.
- Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). Med Care. 1992; 30:473–483. [PubMed: 1593914]
- Ware, JE., Snow, KK., Kosinski, M., Gandek, B. SF-36 Health Survey: Manual and Interpretation Guide. Quality-Metric Incorporated; Lincoln, RI: 2000.
- Wyatt GE, Desmond KA, Ganz PA, Rowland JH, Ashing-Giwa K, Meyerowitz BE. Sexual functioning and intimacy in African American and white breast cancer survivors: A descriptive study. Womens Health. 1998; 4:385–405. [PubMed: 9916546]

Table 1

Health-related quality of life: RAND-36 normative and participant scores (mean ± standard deviation)

RAND-36 subscales	General population norms ^a	Other breast cancer patients: Study 1 (n=863) ^b	Other breast cancer patients: Study 2 $(n=1098)^{C}$	Participants (n=2582)
Physical Health:				
Physical functioning	81.47 ± 24.60	80.31 ± 21.44	80.65 21.32	84.14 ± 18.21
Role limitations—physical	77.77 ± 36.20^d	75.84 ± 34.04	75.79 35.06	$71.06 \pm 37.51 d$
Bodily pain	73.59 ± 24.25	78.51 ± 20.43	78.72 20.98	75.00 ± 22.99
General health	70.61 ± 21.50	73.27 ± 19.82	72.45 20.20	71.49 ± 18.70
Mental Health:				
Mental health	73.25 ± 18.68	75.52 ± 17.51	74.88 17.60	76.74 ± 14.99
Role limitations—emotional	79.47 ± 34.43	78.50 ± 34.52	76.72 34.63 ^e	81.85 ± 31.48^{e}
Vitality	58.43 ± 21.47	60.47 ± 20.29	59.63 21.36	58.81 ± 20.90
Social functioning	81.54 ± 23.74^{d}	86.62 ± 19.82	85.40 20.85	86.72 ± 19.98^{d}

^aNorms for women from the general US population (Ware *et al.*, 2000).

^bGanz study of HRQOL and sexual functioning in breast cancer survivors (Ganz *et al.*, 1998a).

^CGanz study of HRQOL and adjuvant therapy in breast cancer survivors (Ganz *et al.*, 1998b).

 d_{5} -point differences are considered clinically meaningful. Means for participants exceeded this criterion when compared with general population means. Higher score=higher QOL.

 e^{5} -point differences are considered clinically meaningful. The mean for participants exceeded this criterion when compared with comparison study 2.

Table 2

Pearson's correlations: patient characteristics vs. RAND-36 QOL summary scales (n=2582).

	Quality of Life S	ummary Scales
	Physical Health	Mental Health
Demographics:		
Age	-0.063	0.150
Education	0.107	0.033
Ethnicity/race	0.023	0.041
Marital status	0.074	0.094
Anthropometrics: body mass index	-0.277*	-0.135
Health behaviors:		
Alcohol intake	0.137	0.062
Current smoking	-0.012	-0.049
Diet composition ^a	0.107	0.091
Physical activity ^b	0.225*	0.202
Breast cancer variables:		
Cancer stage at diagnosis	-0.039	-0.032
Current tamoxifen use-no/yes	0.054	0.109
Years since diagnosis	0.108	0.096
Treatment: radiation only	0.024	0.048
Chemotherapy only	0.027	-0.010
Both radiation & chemotherapy	-0.034	-0.051
Psychosocial variables:		
Ambivalence over negative emotional expressiveness ${}^{\mathcal{C}}$	-0.172	-0.280*
Center for epidemiologic studies—depression ^{C}	-0.267 *	-0.530*
$\operatorname{Hostility}^{\mathcal{C}}$	-0.173	-0.229*
Life events	-0.211	-0.307*
Negative emotional expressiveness $^{\mathcal{C}}$	-0.006	-0.040
$Ontimism^{\mathcal{C}}$	0.214	0 389*
Poor sleep quality	-0.293	_0.339 *
Sleep quantity (Hours)	-0.058	-0.098
Social strain	-0.230	_0.364 *
	0.216	-0.304
Social support	0.210	0.352
Symptoms:	*	*
Psychological ^C	-0.415	-0.623 *
Pain ^d	-0.582*	-0.351*
Vasomotor ^d	-0.183	-0.169
Genitourinary ^d	-0.169	-0.162
Gastrointestinal ^d	-0.325*	-0.293*

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* Meets MOS criterion for meaningfulness (Pearson's $t \ge 0.23$) (Stewart and Ware, 1992) and are significant at p = 0.001.

^{*a*}Number of NCI daily recommendations met: 30% of energy from fat; \geq 20 g/d fiber; \geq 5 servings/d fruit/vegetables.

^bMetabolic equivalents/week, excluding sleep.

 c Excluded from multiple regression model with Mental Health as DV due to conceptual overlap.

 $d_{\text{Excluded from multiple regression model with Physical Health as DV due to conceptual overlap.}$

Table 3a

Associations between participant characteristics and RAND-36 physical health summary scale scores (multiple linear regression) (*n*=2582)

	В	S.E. B	<i>t</i> -score	<i>p</i> -value
Step 1: forced entry of covariates ^{a,b}				
<i>R</i> ² =0.159				
Step 2: forced entry of covariates ^{a} plus the following participant characteristics ^{c}				
Symptoms: psychological	-10.430	0.824	-12.663	< 0.001
Body mass index	-0.585	0.056	-10.393	< 0.001
Poor sleep quality	-3.048	0.359	-8.497	< 0.001
Physical activity	0.002	0.000	5.249	< 0.001
Depressive symptoms (CES-D-sf)	-6.729	2.658	-2.531	0.011
Social strain	-0.316	0.144	-2.200	0.027
<i>R</i> ² =0.315				

CES-D-sf: Center for epidemiologic studies-depression scale (short form).

^{*a*}All demographic and breast cancer variables in Table 2 plus alcohol intake, smoking, diet composition, ambivalence over negative emotional expressiveness (NEE), hostility, life events, NEE, optimism, sleep quantity, and social support were included in the model.

^bModel accounted for 15.9% of variance in RAND-36 Physical Health score (*F*=24.178, df=20, 2561, *p*<0.001).

^cModel accounted for 31.5% of variance in RAND-36 Physical Health score (F=45.184, df=26, 2555, p<0.001).

Table 3b

Associations between participant characteristics and RAND-36 mental health summary scale scores (multiple linear regression) (*n*=2582)

	В	S.E. B	<i>t</i> -score	<i>p</i> -value
Step 1: forced entry of covariates ^{<i>a</i>,<i>b</i>}				
<i>R</i> ² =0.149				
Step 2: forced entry of covariates ^{a} plus the following participant characteristics ^{c}				
Poor Sleep Quality	-3.842	0.322	-11.944	< 0.001
Life Events	-2.079	0.204	-10.194	< 0.001
Symptoms: Pain	-5.297	0.554	-9.562	< 0.001
Symptoms: Gastrointestinal	-3.615	0.612	-5.906	< 0.001
R ² =0.304				

 a All demographic, anthropometric, health behavior and breast cancer variables in Table 2 plus sleep quantity and vasomotor and genitourinary symptoms were included in the model.

^bModel accounted for 14.9% of variance in RAND-36 Physical Health score (F=24.964, df=18, 2563, p<0.001).

^cModel accounted for 30.4% of variance in RAND-36 Physical Health score (*F*=50.690, df=22, 2559, *p*<0.001).