

## PAPER

# Helping Her Heal: Randomized clinical trial to enhance dyadic outcomes in couples

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**Abstract**

**Objective:** The objective of this study was to test the short-term efficacy of a brief, fully manualized marital communication and interpersonal support intervention for couples facing recently diagnosed breast cancer.

**Methods:** A total of 322 women diagnosed within 6 months with stages 0 to III breast cancer and their 322 spouse caregivers were enrolled. Spouses in the experimental group received five 30- to 60-minute intervention sessions at 2-week intervals by master's-prepared patient educators; controls received the booklet, "What's Happening to the Woman I Love?" Outcomes were assessed at 3, 6, and 9 months using the linear mixed models within an intent-to-treat analysis.

**Results:** Compared with controls, at 3 months, spouse caregivers significantly improved on standardized measures of depressed mood, anxiety, cancer-related marital communication, interpersonal support, and self-care. All differences except depressed mood and anxiety were sustained at 9 months. Wives significantly improved at 3 months on marital communication and positive appraisal of spouses' interpersonal support; gains remained significant at 9 months. Compared with controls on chemotherapy, wives in the experimental group additionally improved on depressed mood and tended to improve on anxiety.

**Conclusions:** A brief, fully manualized intervention delivered directly to spouse caregivers early in the course of their wives' medical treatment improves caregivers' self-care and behavioral-emotional adjustment and wives' positive view of their spouses' support and communication. The brevity and manualized structure of the intervention argue strongly for its scalability, use in cost-sensitive settings, and its potential dissemination through e-health channels.

**KEYWORDS**

cancer, caregiver, marital communication, oncology, randomized clinical trial, self-care, self-efficacy, skill training, spouse, support

## 1 | INTRODUCTION

Spouse caregivers of women with breast cancer suffer substantial distress during initial treatment of their wives' breast cancer that goes well beyond simple "caregiving burden."<sup>1,2</sup> An estimated 22% to 32% of them reach or exceed clinical levels of anxiety or depressed mood or both,<sup>3</sup> and there is early evidence that caregiving can put spouses at risk for dysregulation of their pro-inflammatory and anti-inflammatory pathways.<sup>4,5</sup>

Breast cancer also takes a toll on the couples' relationship, including the quality of marital communication and interpersonal support and marital tension or discord.<sup>2,6-16</sup> Both the quality and type of marital communication about the cancer, including partner supportive responses, significantly affect the diagnosed woman's psychological distress<sup>7,8</sup> and relationship satisfaction.<sup>7</sup>

Spouse caregivers self-describe as being unprepared for all aspects of their role<sup>17</sup>; struggle with what to say and do to support their ill partner<sup>10,18</sup>; commonly misjudge how to help her, emphasizing instrumental, not interpersonal support<sup>19</sup>; struggle with her emotional lability from the cancer and its treatment<sup>10</sup>; and carry serious fears that, despite the best medical treatment, they may lose her to the disease.<sup>20</sup>

Despite the magnitude of distress and the large numbers affected, there has never been a randomized control clinical trial of a fully manualized in-person intervention that is delivered directly to spouse caregivers with hypothesized benefits to both members of the dyad. What we do know is that lengthy, multiple, face-to-face, in-home, or group-delivered interventions conjointly delivered to the dyad have significantly improved patients' and caregivers' anxiety, depressive symptoms, cancer-specific distress, and positive well-being.<sup>14-16,21</sup> However, these interventions are not scalable or sustainable, and none have attempted to benefit the dyad by intervening solely with the spouse caregiver.

### 1.1 | Specific aims

The purpose of the current study was to test the short-term efficacy of a five-session skill- and efficacy-building communication and interpersonal support intervention delivered to spouses with hypothesized benefits to recently diagnosed wives with stages 0 to III breast cancer. Goals were to improve spouse caregivers' and wives' depressed mood, anxiety, and cancer-related marital communication; spouses' behavioral skills and confidence in interpersonally supporting their wife and managing their own cancer-related distress; and increase wives' positive appraisal of spouses' interpersonal support and cancer-related marital communication.

## 2 | METHODS

The study was a two-group randomized control trial with block randomization that was centrally managed by the study's biostatistician using a computer random allocation program. Assessments were carried out at baseline and at 3, 6, and 9 months. Women and their caregivers were eligible if women were diagnosed within 6 months

with in situ or invasive breast cancer (stage 0, I, IIA, IIB, or III), were married or in an intimate relationship with her spouse (either gender) caregiver, read and wrote English among their languages of choice, and lived within 100 miles of the study center.

After Human Subjects' approval at the study center and each recruitment site, the data collection team obtained signed informed consent from caregivers and patients and baseline measures in couples' homes. Data collectors, study participants, site intermediaries, and referring medical providers were masked on randomization status for the duration of the study. Dosage and fidelity were monitored by comparing each digitally recorded intervention session against standardized session-specific performance criteria.

### 2.1 | Experimental intervention

The *Helping Her Heal* (HHH) Program consisted of five fully scripted, psychoeducational sessions delivered in person to the spouse caregiver every 2 weeks by a master's-prepared patient educator (nurse, certified health educator, or social worker). The theoretical basis of the intervention was derived from the relational model of adjustment to cancer, an extension of family systems theory for dyads and families affected by cancer,<sup>2,7,8,11-13,22-26</sup> and Bandura's social cognitive theory.<sup>27-29</sup> Each session began with a brief didactic text to frame the session, and all sessions incorporated written and interactional assignments between the caregiver and patient educator. Content was unique to each session, complemented by at-home exercises the caregiver practiced with the patient educator, and sessions lasted 30 to 60 minutes each. See details in Lewis et al.<sup>30</sup>

### 2.2 | Control group

Participants randomized to the control group were mailed a 16-page booklet available in the public domain, "What's Happening to the Woman I Love?" which described what the spouse caregiver could do to emotionally and physically support his wife, identified strategies for strengthening their relationship, and suggested methods the caregiver could use to decrease distress in their caregiver role.

### 2.3 | Study measures

Diagnosis, demographic, and treatment-related data were obtained from the medical record and self-report.

#### 2.3.1 | Depressed mood

Depressed mood was measured by the Center for Epidemiologic Studies-Depression (CES-D) Scale, a 20-item scale that measures the recent occurrence of symptoms of depression.<sup>31,32</sup> Internal consistency reliability and validity are well established, ranging between 0.84 and 0.85.<sup>31-33</sup> Internal consistency reliability for the study sample was 0.892 for caregivers and 0.894 for patients.

### 2.3.2 | Anxiety

Spouse caregivers' and patients' anxiety was measured by the state component of the Spielberger State-Trait Anxiety Inventory (STAI), a 20-item self-report questionnaire that evaluates feelings of apprehension, tension, nervousness, and worry "right now, at this moment."<sup>34,35</sup> Reliability and validity are well established.<sup>36</sup> Internal consistency reliability for the study sample was 0.935 for caregivers and 0.945 for patients.

### 2.3.3 | Marital communication

Marital communication was measured by the Mutuality and Interpersonal Sensitivity Scale (MIS), a self-report questionnaire that measures both the content and ways in which couples communicate with each other about the breast cancer.<sup>20,24</sup> The measure has two subscales: open communication, eg, "We spend a lot of time talking about how things are going with the breast cancer," and expressing sad feelings, eg, "We don't talk together about the sadness I feel about the breast cancer." Higher scores denote a higher quality of marital communication about the cancer. The internal consistency reliabilities for wives' and spouses' open communication subscale for the study sample were 0.92 and 0.86, respectively, and 0.88 and 0.82 for the expressing sad feelings subscale for wives and spouses, respectively.

### 2.3.4 | Spouse's skills

Spouse's skills were measured by the What I Do for Her Checklist, a spouse-reported measure developed by the study team that describes the specific communication and interpersonal support skills the spouse carries out with the wife related to the breast cancer. The wife support subscale (six items) measures spouses' ways of behaviorally interacting with her about the cancer, eg, "I ask my wife/partner about specific ways I can be supportive to her about her breast cancer." The self-care subscale (six items) measures spouses' ways of managing their own cancer-related stress, eg, "I take regular time out for myself." The scale was assessed for content validity by three expert clinicians. Construct validity was evaluated by examining its correlation with spouses' depressed mood, anxiety, self-efficacy, and wife-reported perceived support. The internal consistency reliability for the study sample was 0.64 (wife support subscale) and 0.51 (self-care subscale).

### 2.3.5 | Self-efficacy scale

Spouses' self-efficacy was measured by the Cancer Self-Efficacy Scale (CASE), a 19-item self-report measure of the spouse's degree of self-confidence to support his wife and carry out his own self-care.<sup>20,24</sup> The questionnaire consists of two subscales: a wife-focused subscale and a self-care-focused subscale.<sup>30,37</sup> The wife-focused subscale (14 items) measures spouses' confidence in talking with the patient about her cancer-related concerns and be supportive, eg, "I know what to do to be supportive to my wife/partner about the breast cancer." The self-care subscale (five items) measures caregivers' confidence in helping themselves deal with the demands and challenges of the cancer, eg, "I know what resources to use to help me personally cope

with my wife's breast cancer." The internal consistency reliability for the total scale was 0.952 for the study sample and 0.949 for the wife-focused and 0.810 for the self-care subscales.

### 2.3.6 | Wife's appraisal of spouse's support

The What He Does for Me Questionnaire is an 18-item measure of support that describes the wife's perception of specific, observable behaviors of support she receives from her spouse related to her breast cancer. Example items read, "My husband/partner listens to me when I tell him/her sad or negative things about my breast cancer" and "My husband/partner starts up conversations with me when I'm sad or worried about my breast cancer." The scale's internal consistency reliability for the study sample was 0.88.

## 2.4 | Data analytic strategy

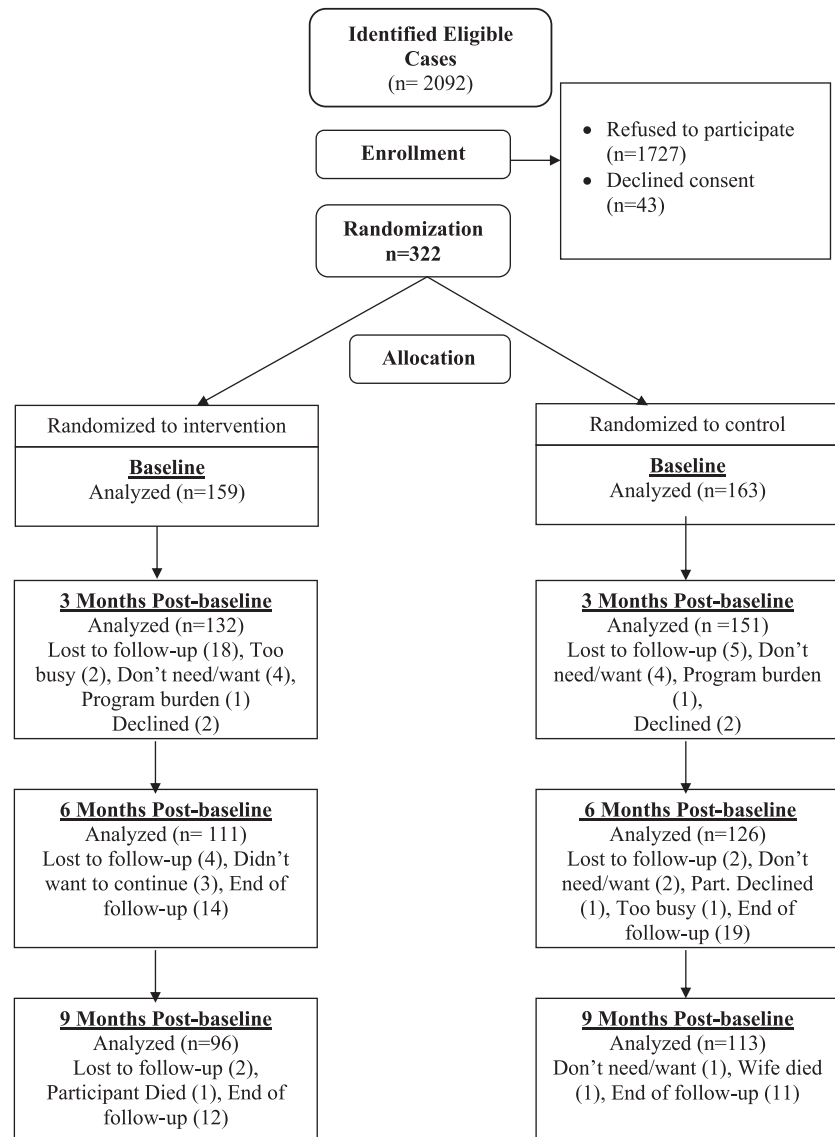
Prior to evaluating efficacy, data were inspected for sampling distributions, outliers, covariates, and floor and ceiling effects. All measures were approximately normally distributed. Primary tests of efficacy examined differences between groups at 3 months. Changes between baseline and 6 and 9 months evaluated the stability of changes. Linear mixed models, based on maximum likelihood estimation, were used to evaluate efficacy.<sup>38,39</sup> Pretreatment equivalence between experimental and control groups was examined at baseline; groups were comparable on all demographic, treatment, and outcome measures.

## 2.5 | Target sample size and power calculations

Prior to conducting the study, a sample size of 220 (110 in each group) was calculated a priori to detect an effect size of 0.25 to 0.5 on all spouse caregivers' and patients' outcomes assessed at 3 months postbaseline. Power calculations were based on the two-tailed *t* tests,  $P = 0.05$ .

## 2.6 | Sample

A total of 2092 eligible spouse caregivers were identified of which 322 enrolled, 159 were randomized to experimental, and 163 were randomized to control. See Figure 1. Patients were diagnosed an average of 3.3 months (SD 1.2) at baseline, and 123 (45.1%) were treated with non-breast-conserving surgery (partial, total, or bilateral mastectomy). Patients had primarily stage I breast cancer 126 (39.4%); 114 (35.6%) had stage II disease; 30 (9.4%) had stage III disease; and 52 (15.6%) had in situ (stage 0) disease. More than half (59%) of the women received adjuvant chemotherapy or radiation therapy or a combination during the study. Patients were primarily Caucasian (285; 88.5%); seven (2.2%) were Hispanic; 13 (4.0%) were Asian; two (0.6%) were African American; and 15 (4.7%) were other ethnicities, including Native American and Pacific Islander. Patients were primarily college educated (72%), averaged 53.1 years of age (SD 11.4), and married an average of 23.1 (SD 12.9) years. At baseline, 44.4% scored at or above 16 on the CES-D, and 36.3% scored at or above 40 on the STAI, scores indicative of distress.



**FIGURE 1** Study participant flow sheet

Spouse caregivers were primarily Caucasian (286; 88.8%); seven (2.2%) were Hispanic; 14 (4.3%) were Asian; five (1.6%) were African American; and 10 (3.1%) were other ethnicities, including Native American and Pacific Islander. Caregivers averaged 54.8 years of age (SD 12.2) were primarily college educated (228; 70.8%); and 234 (72.7%) were working full time or part-time at time of study participation. At baseline, 32.3% of the spouse caregivers scored at or above 16 on the CES-D, and 29.8% scored at or above 40 on the STAI.

### 3 | RESULTS

Tables 1 and 2 contain study results for spouse caregivers and diagnosed wives at baseline and at 3, 6, and 9 months. Prior to analysis, comparisons were made between study completers and those who withdrew. There was one significant difference between these two groups on demographic, treatment, and outcome measures. Patients who withdrew had significantly higher anxiety scores on the STAI (mean 41.6/SD 14.4) than do patients who completed 3-month assessments (mean 35.8/SD 11.8). Comparisons were also made

between participants who withdrew the study and study completers and between study participants randomized to the experimental group who withdrew after one or more intervention sessions compared with those who completed all five intervention sessions. There were no significant differences between withdrawals between baseline and 3 months on demographic, treatment, or outcome variables or between those who withdrew from the intervention after one or more sessions and those who completed all five intervention sessions.

#### 3.1 | Spouse caregivers' outcomes

##### 3.1.1 | Depressed mood

Depressed mood in spouses in the experimental group, compared with controls, significantly declined at 3 months (mean 8.83 vs mean 10.68;  $P < 0.006$ ; Cohen's  $d = 0.29$ ). By 6 and 9 months, there was no significant difference between experimental and control groups.

**TABLE 1** Spouses' measures over time by randomization group

	Baseline		3 mo Postbaseline		6 mo Postbaseline		9 mo Postbaseline		Cohen's <i>d</i> / <i>P</i> Value <sup>c</sup>
	Control	Experimental	Control	Experimental	Control	Experimental	Control	Experimental	
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	
Depressed mood	12.10 (0.6)	12.48 (0.6)	10.68 (0.7)	8.83 (0.7)	10.51 (0.7)	9.61 (0.8)	9.36 (0.8)	8.40 (0.9)	0.17/0.199
Anxiety	33.46 (0.8)	34.82 (0.8)	32.64 (0.8)	30.88 (0.9)	32.56 (0.9)	31.87 (0.9)	30.91 (0.9)	30.50 (1.0)	0.18/0.096
Marital communication									
Total scale	86.68 (0.9)	85.40 (0.9)	86.45 (0.9)	89.40 (1.0)	85.18 (1.0)	87.04 (1.1)	83.50 (1.2)	86.61 (1.2)	0.40/0.004
Open communication	30.34 (0.4)	30.09 (0.4)	30.68 (0.4)	31.84 (0.4)	30.07 (0.4)	30.84 (0.5)	29.89 (0.5)	31.41 (0.5)	0.38/0.006
Expressing sad feelings	31.49 (0.4)	30.57 (0.4)	31.44 (0.4)	32.63 (0.5)	30.90 (0.5)	31.79 (0.5)	30.28 (0.5)	31.56 (0.6)	0.39/0.002
Skills									
Wife support	47.24 (0.4)	47.23 (0.4)	48.41 (0.4)	52.10 (0.4)	48.33 (0.4)	50.67 (0.4)	48.20 (0.4)	50.67 (0.5)	0.48/<0.001
Self-care	16.43 (0.3)	16.73 (0.3)	17.20 (0.3)	19.45 (0.3)	17.15 (0.3)	19.48 (0.3)	17.41 (0.3)	19.58 (0.3)	0.52/<0.001
Self-efficacy									
Total scale	118.31 (1.6)	119.29 (1.6)	143.92 (1.7)	154.88 (1.7)	145.78 (1.8)	152.06 (1.9)	146.28 (2.0)	154.05 (2.2)	0.25/0.018
Self-care	31.81 (0.5)	31.71 (0.5)	38.05 (0.5)	40.38 (0.5)	38.23 (0.6)	40.39 (0.6)	38.75 (0.6)	40.99 (0.6)	0.29/0.017
Wife focused	86.50 (1.3)	87.58 (1.3)	105.85 (1.3)	114.47 (1.4)	107.55 (1.4)	111.61 (1.5)	107.51 (1.6)	113.02 (1.7)	0.21/0.046

<sup>a</sup>Cohen's *d*/*P* value denotes the effect size and *P* value for the change from baseline to 3 months by randomization group.

<sup>b</sup>Cohen's *d*/*P* value denotes the effect size and *P* value for the change from baseline to 6 months by randomization group.

<sup>c</sup>Cohen's *d*/*P* value denotes effect size and *P* value for the change from baseline to 9 months by randomization group.

**TABLE 2** Wives' measures over time by randomization group

	Baseline		3 mo Postbaseline		6 mo Postbaseline		9 mo Postbaseline		Cohen's <i>d</i> P value <sup>c</sup>
	Control	Experimental	Control	Experimental	Control	Experimental	Control	Experimental	
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	
Depressed mood	14.62 (0.7)	15.83 (0.7)	13.92 (0.7)	13.12 (0.8)	11.04 (0.8)	13.00 (0.8)	10.60 (0.8)	11.02 (0.9)	0.06/0.510
Anxiety	35.44 (0.9)	37.72 (0.9)	32.53 (0.9)	34.07 (0.9)	31.29 (1.0)	35.04 (1.0)	31.39 (1.0)	32.86 (1.0)	0.02/0.593
Marital communication									
Total scale	87.22 (1.1)	85.44 (1.2)	86.03 (1.2)	87.07 (1.2)	84.08 (1.3)	83.69 (1.4)	81.31 (1.5)	82.72 (1.5)	0.31/0.074
Open communication	36.93 (0.5)	36.45 (0.5)	37.21 (0.5)	37.51 (0.5)	36.67 (0.5)	36.34 (0.5)	36.11 (0.6)	36.48 (0.6)	0.18/0.269
Expressing sad feelings	32.90 (0.5)	32.12 (0.5)	33.19 (0.5)	33.44 (0.5)	32.53 (0.6)	32.60 (0.6)	31.17 (0.6)	32.24 (0.7)	0.36/0.032
Appraised spouse support	65.08 (0.8)	63.40 (0.9)	64.34 (0.9)	66.24 (0.9)	64.57 (1.0)	64.26 (1.0)	62.62 (1.1)	64.55 (1.2)	0.37/0.009

<sup>a</sup>Cohen's *d*/P value denotes effect size and P value for change from baseline to 3 months by randomization group.

<sup>b</sup>Cohen's *d*/P value denotes effect size and P value for change from baseline to 6 months by randomization group.

<sup>c</sup>Cohen's *d*/P value denotes effect size and P value for change from baseline to 9 months by randomization group.

### 3.1.2 | Anxiety

Anxiety significantly decreased in the experimental group, compared with controls, at 3 months (mean 30.88 vs mean 32.64;  $P < 0.001$ ; Cohen's  $d = 0.36$ ) and at 6 months (mean 31.87 vs mean 32.56;  $P = 0.033$ ; Cohen's  $d = 0.23$ ). By 9 months, experimental group spouses' anxiety tended to be lower than that of controls but was no longer significantly different (mean 30.50 vs mean 30.91,  $P = 0.096$ ; Cohen's  $d = 0.18$ ).

### 3.1.3 | Marital communication

Spouses in the experimental group, compared with controls, significantly improved on both dimensions of cancer-related marital communication. Open communication (mean 31.84 vs mean 30.68;  $P = 0.003$ ; Cohen's  $d = 0.32$ ) and expressing sad feelings (mean 32.63 vs mean 31.44;  $P < 0.001$ ; Cohen's  $d = 0.36$ ) significantly improved at 3 months. Differences were sustained at 6 months (mean 31.79 vs mean 30.90;  $P = 0.004$ ; Cohen's  $d = 0.29$ ) and 9 months (mean 31.56 vs mean 30.28;  $P = 0.002$ ; Cohen's  $d = 0.39$ ).

### 3.1.4 | Skills

Compared with controls, spouses in the experimental group significantly improved on both dimensions of spouses' skills, What I Do for Her Checklist. The wife support subscale significantly increased at 3 months (mean 52.10 vs mean 48.41;  $P < 0.001$ ; Cohen's  $d = 0.74$ ) and remained significantly greater than that of controls at both 6 months (mean 50.67 vs mean 48.33;  $P < 0.001$ ; Cohen's  $d = 0.48$ ) and 9 months (mean 50.67 vs mean 48.20;  $P < 0.001$ ; Cohen's  $d = 0.48$ ).

Spouses' self-care skills were significantly greater in the experimental group at 3 months (mean 19.45 vs mean 17.20;  $P < 0.001$ ; Cohen's  $d = 0.54$ ). Changes were sustained at 6 months (mean 19.48 vs mean 17.15;  $P < 0.001$ ; Cohen's  $d = 0.54$ ) and 9 months (mean 19.58 vs mean 17.41;  $P < 0.001$ ; Cohen's  $d = 0.52$ ).

### 3.1.5 | Cancer self-efficacy

Compared with controls, spouses in the experimental group significantly improved at 3 months on both dimensions of self-efficacy: wife focused (mean 114.47 vs mean 105.85;  $P < 0.001$ ; Cohen's  $d = 0.39$ ) and self-care focused (mean 40.38 vs mean 38.05;  $P < 0.001$ ; Cohen's  $d = 0.34$ ). Gains in spouses' self-care were sustained at 6 months (mean 40.39 vs mean 38.23;  $P = 0.006$ ; Cohen's  $d = 0.30$ ) and 9 months (mean 40.99 vs mean 38.75;  $P = 0.17$ ; Cohen's  $d = 0.29$ ). Initial gains at 3 months in the spouse's confidence in helping his wife manage were not sustained at 6 months but were significantly improved at 9 months compared with baseline (mean 113.02 vs 107.51;  $P = 0.046$ ; Cohen's  $d = 0.21$ ).

## 3.2 | Wives' outcomes

### 3.2.1 | Depressed mood

There were no significant differences in depressed mood between wives in the experimental and control groups at 3, 6, or 9 months.



### 3.2.2 | Anxiety

There were no significant differences on anxiety between wives in the experimental and control groups at 3, 6, or 9 months.

### 3.2.3 | Marital communication

Compared with controls, wives in the experimental group significantly improved on the total scale score of marital communication at 3 months (mean 87.07 vs mean 86.03;  $P = 0.017$ ; Cohen's  $d = 0.24$ ) and tended to increase on the expressing sad feelings subscale (mean 33.44 vs mean 33.19;  $P = 0.084$ ; Cohen's  $d = 0.19$ ). Although subscale scores on expressing sad feelings were not significantly different for wives in the experimental compared with the control group (mean 32.60 vs mean 32.53;  $P = 0.26$ ; Cohen's  $d = 0.18$ ) at the initial postintervention assessment or at 6 months, by 9 months, wives' expression of sad feelings was significantly improved compared with that of controls (mean 32.24 vs mean 31.17;  $P = 0.032$ ; Cohen's  $d = 0.36$ ). The pattern was for wives in the control group to decrease in their expression of sad feelings while wives in the experimental group increased. Subscale analyses showed no significant changes on the open communication subscale at 3, 6, or 9 months.

### 3.2.4 | Appraised spouse support

Compared with controls, wives in the experimental group increased in their positive appraisal of spouses' interpersonal support. Improvements were significant at 3 months (mean 66.24 vs mean 64.34;  $P < 0.001$ ; Cohen's  $d = 0.39$ ) and at 9 months (mean 64.55 vs mean 62.62;  $P = 0.009$ ; Cohen's  $d = 0.37$ ).

## 4 | DISCUSSION AND CONCLUSIONS

The HHH Program is the first randomized trial of a skill-building cancer-related marital communication and interpersonal support intervention delivered directly to spouse caregivers with significant benefits to both caregivers and wives. At 3 months, the primary assessment period, the program significantly improved spouses' depressed mood, anxiety, marital communication, interpersonal support to his wife, his self-care, and his self-confidence compared with those of controls. Effect sizes ranged from small to moderate: 0.29 to 0.74. Most significant improvements at 3 months were sustained at 6 and 9 months.

Improvements were more limited for wives than spouses. Compared with controls, wives in the experimental group had significantly improved marital communication about the cancer and significantly higher positive appraisal of spouses' interpersonal support. However, the intervention did not significantly affect wives' depressed mood or anxiety. Three plausible causes were considered—program failure, measurement failure, and design failure—none of which explained the differential impact of the intervention on some but not all wives' outcomes. We speculated that analyses on the total sample were potentially insensitive to changes in a subgroup of women at potentially high risk for anxiety and depressed mood: women on

chemotherapy. A single post hoc analysis was computed comparing women on chemotherapy in the experimental with those in the control group. Prior to analysis, pretreatment equivalence on background, treatment, and baseline measures was confirmed. Compared with controls, women in the experimental group had significantly decreased depressed mood (mean 11.71 vs mean 14.24;  $P = 0.05$ ; effect size  $d = 0.34$ ) and significantly improved scores on the total scale score on marital communication (mean 88.77 vs mean 87.16;  $P = 0.04$ ; Cohen's  $d = 0.46$ ), on the openness of their communication with their spouse about the cancer (mean 37.97 vs mean 37.07;  $P = 0.05$ ; Cohen's  $d = 0.39$ ), and on the degree to which they were able to express sad or negative thoughts and feelings about the cancer (mean 34.15 vs mean 32.92;  $P = 0.008$ ; Cohen's  $d = 0.56$ ). There was also a tendency for wives' anxiety to be reduced, but that change was not statistically significant. These differences between experimental and control women on chemotherapy are clinically significant given that both the effect sizes and the improvements were achieved by only intervening with the spouse.

Contrary to Scott's study that required the concurrent presence of patient and caregiver,<sup>25</sup> current study results show that directly intervening with the spouse can improve adjustment of both members of the dyad. Contrary to a study by Manne's team,<sup>21</sup> the current intervention did not require conjoint therapy, mutual disclosure, nor group delivery.

### 4.1 | Study limitations

Caution is needed in interpreting results. The sample was biased toward well-educated, middle-class couples in long-term heterosexual marriages; results may not generalize to other populations. The measure of spouses' skills had low internal consistency reliability. Future studies need to test efficacy on a more diverse population, use a more reliable measure of spouses' skills, and use less costly methods of delivery.

### 4.2 | Clinical implications

Results suggest the potential benefits of directly intervening with spouse caregivers early during treatment for breast cancer. Spouses' sustained positive outcomes on marital adjustment and communication and wives' sustained positive appraisal of spouses' interpersonal support and marital communication are clinically significant results given that all were achieved in approximately 3.3 hours of contact time between the spouse and patient educator. The significant improvements in marital communication and depressed mood for wives on adjuvant chemotherapy reinforce the importance of enrolling caregivers early during treatment.

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## CONFLICT OF INTEREST

The authors have no conflicts of interest to report.

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