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ORIGINAL RESEARCH

Supportive Intervention for Unmet Needs Among Breast Cancer Patients and Their Spousal Caregivers: A Randomized Controlled Trial

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Purpose: This study aims to evaluate the effectiveness of a supportive intervention program designed based on Existence-Relatedness -Growth theory and the Supportive Care Needs Framework in reducing unmet needs among breast cancer patients and their spouse caregivers.

Patients and Methods: This study was a two-arm, single-blind randomized controlled trial. Between December 2024 and August 2025, 122 breast cancer patient–spousal caregiver dyads were recruited from the Affiliated Hospital of Jiangnan University and randomly assigned to an intervention or control group (61 dyads each). The intervention group received a 6-week dyadic supportive care program targeting unmet needs, delivered by the principal investigator in weekly 60-minute sessions. The control group received routine care. Primary outcome was unmet needs; secondary outcomes included communication problems, quality of life, anxiety, and depression. All outcomes were assessed at baseline and post-intervention. Linear mixed models analyzed the primary outcome, while multilevel models evaluated intervention effects on secondary outcomes.

Results: A total of 111 breast cancer patient-spouse caregiver dyads completed the intervention (56 in the intervention group and 55 in the control group). Linear mixed model analysis showed that the intervention reduced unmet needs in breast cancer patient–spousal caregiver dyads over time compared with the control group (group × time interaction: β=−4.90, p<0.001). Patients and spousal caregivers exhibited different trajectories of unmet needs over time (time × role interaction: β=3.71, p=0.004). Multilevel model analysis showed that, compared with the control group, the intervention group demonstrated significant improvements in couple communication problems, quality of life, anxiety, and depression (all p<0.05).

Conclusion: The unmet needs supportive intervention program for breast cancer patient-spousal caregiver dyads can effectively reduce unmet needs and enhance couple communication, thereby improving their quality of life and alleviating anxiety and depression.

Keywords: breast cancer, unmet needs, supportive care, spouse caregivers, dyadic intervention

Introduction

Breast cancer (BC) is one of the most common malignant tumors among women worldwide.[1] According to data released by the International Agency for Research on Cancer, approximately 2.3 million new breast cancer cases were diagnosed globally in 2022, with about 666,000 deaths.[2] China accounted for 21.11% of new cases and 11.96% of deaths worldwide, indicating a substantial breast cancer burden in the country.[3] With advances in early screening and treatment

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methods, the five-year survival rate for breast cancer patients has reached as high as 90%, making their quality of life and psychological needs a focal point of public attention.[4]

BC patients experience various physical and psychological symptoms during treatment, such as upper limb dysfunction, chemotherapy-induced nausea and vomiting, anxiety, and depression.[5,6] As primary caregivers, spouses not only endure physical exhaustion but also face psychological strain. This includes accompanying patients to examinations and treatments, managing work and household responsibilities, worrying about their spouse's health, and fearing the loss of their partner.[7,8] These negative factors give rise to numerous unmet needs(UN) among BC patient-spouse caregiver dyads. Specifically, the most frequently reported unmet needs by patients involve health information, psychological and emotional support, social support networks, sexuality and intimacy issues, as well as personal growth and development.[9] For spouse caregivers, unmet needs include communication with healthcare providers and information provision, as well as the need for psychological support to cope with caregiving stress.[10,11] Research indicates that a significant interdependence exists between cancer patients and their spouse caregivers, with their unmet needs mutually influencing each other.[12] Prolonged unmet needs significantly impair the quality of life for BC couples and exacerbate psychological distress, manifesting as diminished work performance, impaired family and social relationships, and increased anxiety and depression.[13] Concurrently, physical symptoms such as elevated blood pressure, headaches, and sleep disturbances are also likely to emerge.[14]

Current interventions aimed at improving health outcomes for both spouses of cancer patients primarily include enhancing communication between partners, mental health education, and coping skills training.[15] These measures effectively alleviate psychological stress for both patients and spouses, and to some extent improve marital relationships and quality of life.[16,17] However, current research predominantly focuses on common cancer types such as colorectal and prostate cancer. Interventions addressing unmet needs in BC couples often concentrate on individual patients, with limited systematic research targeting the needs of spouse caregivers. Therefore, there is an urgent need to develop dual-collaborative intervention models that simultaneously address the needs of both BC spouses, aiming to enhance the overall quality of life for the entire family.

The ERG (Existence-Relatedness-Growth) theory, proposed by American psychologist Professor Clayton Alderfer, is an extension and simplification of Maslow's hierarchy of needs.[18,19] This theory categorizes needs into three levels: Existence needs, Relatedness needs, and Growth needs. The Supportive Care Needs Framework (SCNF) was proposed by Dr. Fitch in 2008, provides a comprehensive framework for understanding the supportive care needs of cancer patients and their caregivers.[20] It encompasses seven dimensions: physical needs, psychological needs, social needs, emotional needs, spiritual needs, informational needs, and practical needs.

This study integrates the ERG theory with the SCNF framework to guide the design of a supportive intervention program for unmet needs among breast cancer patient-spouse caregiver dyads. Specifically, existence needs within the ERG theory correspond to the physical and practical needs within the SCNF framework, encompassing practical issues such as symptom management, physical recovery, and economic burden. Relatedness needs primarily involve emotional and social support, aligning with the psychological, emotional, and social needs within the SCNF framework. As breast cancer dyads often experience emotional distress and social isolation throughout the disease trajectory, strengthening emotional communication and social support is essential. Growth needs focus on individuals' spiritual and cognitive development, corresponding to the spiritual and informational needs within the SCNF framework. In the process of providing supportive care for patients and their spouse caregivers, both parties require not only informational support to enhance their understanding of the disease, but also opportunities for psychological and spiritual self-growth and adaptation.

Through this integration, the SCNF framework is utilized to systematically identify the multidimensional supportive care needs of breast cancer dyads across various stages of the disease, while the ERG theory provides a theoretical perspective for layering and prioritizing these needs. Consequently, the intervention content was structured into three corresponding modules targeting existence-related needs, relatedness-related needs, and growth-related needs, and was implemented as a dyadic intervention administered to both patients and their spouse caregivers. The specific model of the ERG-SCNF theoretical framework is illustrated in Figure 1.

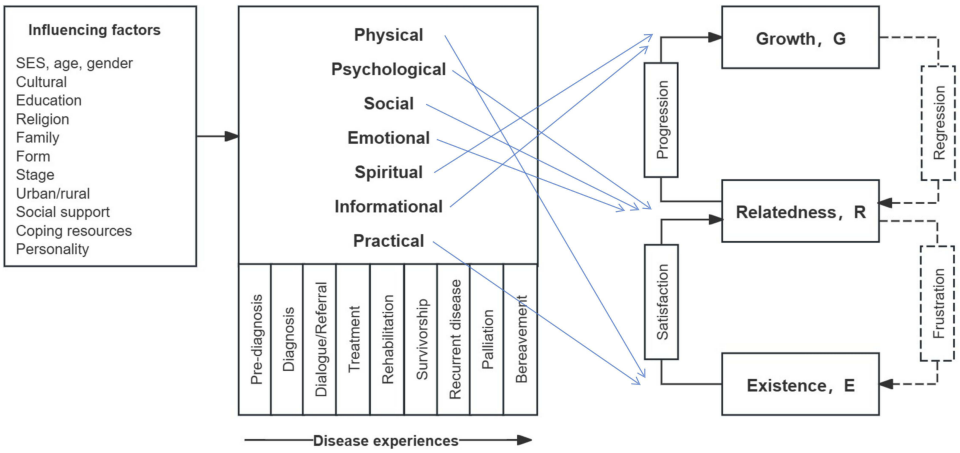

Figure 1 ERG-SCNF theoretical framework.
Note: The blue arrows represent the correspondence between the ERG theory and the SCNF framework.

This study aims to evaluate a dyadic supportive care intervention grounded in the ERG–SCNF theoretical framework. We hypothesize that the intervention will reduce unmet needs, improve communication, alleviate anxiety and depression, and enhance quality of life in both breast cancer patients and their spouse caregivers.

Materials and Methods

Study Design and Participants

This study employed a double-arm, single-blind randomized controlled trial design. From December 2024 to August 2025, BC patients and their spousal caregivers from the Breast Surgery Department of the Affiliated Hospital of Jiangnan University were recruited using a convenience sampling method. Inclusion criteria were as follows: (1) Patients with a pathological diagnosis of breast cancer and stable disease; (2) Their spouse serving as the primary caregiver (undertaking the main caregiving responsibilities); (3) Both parties were adults (> 18 years old); (4) At least one member of the dyad owned and was able to operate a mobile phone; (5) Both members of the dyad were aware of the diagnosis and voluntarily agreed to participate in the study. Exclusion criteria were as follows: (1) Either member of the dyad was diagnosed with a severe physical or psychological condition; (2) The subject had participated in or was currently participating in other similar studies.

Calculation of Sample Size

The sample size was calculated using G*Power 3.1. Based on a previous randomized controlled trial reporting a between-group effect size of Cohen's d= 0.60 for patient unmet supportive care needs.[21] With a two-tailed α of 0.05 and a power of 0.80, 90 BC patient–spousal caregiver dyads were required. Accounting for an anticipated 20% dropout rate, the total sample size was set at 108 dyads. Ultimately, 122 dyads were recruited, with 61 dyads allocated to each group.

Randomization and Blinding

During the recruitment phase, two graduate nursing students preliminarily screened eligible breast cancer patients and their spouse caregivers by reviewing electronic medical records of inpatients in the Breast Surgery Department. Following the initial screening, nurses from the department introduced the study to potential participants and sought their willingness to participate. After providing written informed consent, baseline data (T0) were collected by a graduate nursing student who was not involved in the intervention delivery. Participants were then randomly assigned to either the intervention group or the control group in a 1:1 ratio using the Research Randomizer software (https://www.randomizer.org/).

Intervention

Intervention Group

The intervention team consisted of one graduate supervisor, one breast surgeon, one rehabilitation physician, one oncology psychologist, one head nurse of the breast surgery department, one specialized breast surgery nurse, and four graduate nursing students. The primary implementer was the investigator. The graduate supervisor was responsible for overall management and coordination, overseeing the design and implementation of the intervention program. The physicians and psychologist provided treatment, rehabilitation, and psychological guidance, respectively. The head nurse was in charge of quality control during the intervention process. Under the training of the specialized nurse, the graduate nursing students carried out the specific intervention tasks and were responsible for data collection.

Prior to this study, a multi-step process was undertaken to develop the intervention program. First, qualitative interviews were conducted with 15 BC patient–spousal caregiver dyads to explore their unmet needs when coping with the disease together. Based on existing need-based interventions for cancer couples and discussions within the research team, a supportive intervention program for BC patient–spousal caregiver dyads was initially developed. Subsequently, two rounds of Delphi expert consultations were conducted. Finally, a pilot study was performed to evaluate the feasibility and acceptability of the program, leading to the finalized intervention protocol. The entire intervention process was guided by the ERG-SCNF theoretical framework.

Based on these findings, the unmet needs of BC couples were categorized into six dimensions: disease-related information needs, physical needs, psychological needs, practical support needs, relationship and communication needs, and growth and development needs. These dimensions were mapped onto the ERG theory as follows: disease-related information, physical, and practical support needs correspond to existence needs; psychological, relationship, and communication needs correspond to relatedness needs; and growth and development needs correspond to growth needs. Accordingly, six intervention themes were developed: (1) comprehensive analysis of disease information, (2) pathways to physiological healing, (3) restoring psychological balance, (4) practical support enhancement, (5) optimizing marital relationships, and (6) exploring inner growth.

The intervention consisted of six sessions delivered once per week, each lasting approximately 60 minutes, and was conducted in a one-to-one format. During the first session, the interventionist met face-to-face with the BC patient–spousal caregiver dyad to collect basic information, introduce BC-related information, answer questions, alleviate negative emotions, and establish rapport with the participants. Sessions 2 to 5 were delivered either face-to-face or via WeChat according to participants' needs and preferences, and included a review of homework or exercises from the previous session. After the sixth session, the interventionist guided participants in reviewing key course content and important caregiving skills, encouraged them to share perceived benefits and personal changes, and assisted them in jointly setting future goals and plans. Detailed intervention content is presented in Supplementary Table 1.

To ensure the quality of the intervention, all team members received standardized training prior to its commencement. Throughout the intervention process, the research team held regular meetings to promptly discuss and resolve various issues encountered during implementation, thereby ensuring the consistency and smooth progression of the intervention measures.

Control Group

The control group received usual care, which primarily included health education for BC patients and their spousal caregivers, answering questions related to treatment and nursing care, and providing guidance on home-based diet and exercise. No supportive care intervention targeting the unmet needs of BC patient–spousal caregiver dyads was provided.

Measures

General Information Questionnaire

The general demographic and clinical information collected in this study included patients' age, educational level, religious belief, employment status, monthly household income per capita, type of medical insurance, years of marriage, marital quality, presence of children, clinical stage, time since diagnosis, and current treatment modality. For spousal caregivers, data were collected on age, educational level, religious belief, employment status, and health status.

Unmet Needs Questionnaire

The Survivor Unmet Needs Survey short-form (SF-SUNS) was used to assess the level of unmet needs among breast cancer patients. This scale was translated and revised by Yan et al[22] The Chinese version of SF-SUNS encompasses four dimensions: information needs, work and financial needs, access to care or continuity of care needs, and sharing and emotional needs, comprising 30 items in total. Scoring uses a 5-point Likert scale, with total scores ranging from 0 to 120. Higher scores indicate more significant unmet needs. The scale demonstrated excellent internal consistency, with a Cronbach's α coefficient of 0.894 overall and coefficients ranging from 0.703 to 0.812 across dimensions.

The Support Person's Unmet Needs Survey short-form (SF-SPUNS) was used to assess the level of unmet needs among spousal caregivers. The scale was translated and revised by Han et al[23] The Chinese version of the SF-SPUNS consists of 21 items across five dimensions: information needs, concerns about the future, work and financial needs, access to and continuity of healthcare, and personal and emotional needs. A 5-point Likert scoring method was adopted, with a total score ranging from 0 to 84, where higher scores indicate a greater level of unmet needs among caregivers. The modified scale demonstrated excellent internal consistency, with an overall Cronbach's α of 0.90 and subscale Cronbach's α values ranging from 0.84 to 0.92.

Cancer-Related Communication Problems within Couples Scale (CRCP)

The scale was translated and revised by Li et al[24] The CRCP scale consists of 15 items and uses both positively and negatively worded scoring. For patients, items 1, 6, 7, 9, and 11 are scored positively, whereas the remaining items are reverse scored. For spousal caregivers, items 1, 6, 7, 9, 11, and 13 are scored positively, and the others are reverse scored. Higher total scores indicate greater difficulties in communication between couples coping with cancer. The Cronbach's α coefficients of the scale among Chinese cancer patients and their spousal caregivers were 0.805 and 0.737, respectively, demonstrating satisfactory reliability and validity.[24]

Medical Outcomes Study 12-Item Short-Form (MOS SF-12)

The scale consists of 12 items covering two dimensions: physical health and mental health. Item 2 is reverse scored, while all other items are positively scored. The dimension scores are calculated using the standard scoring algorithm of the SF-12, with higher scores indicating better health status in the corresponding dimension. The Cronbach's α coefficients for the two dimensions were 0.88 and 0.85, respectively, and the scale has also demonstrated good reliability and validity among the Chinese population.[24,25]

Hospital Anxiety and Depression Scale (HADS)

This assessment tool consists of two independent subscales: the anxiety subscale and the depression subscale, each comprising seven items. Items 1, 3, 5, 7, 9, 11, and 13 constitute the anxiety subscale (HADS-A), while items 2, 4, 6, 8, 10, 12, and 14 constitute the depression subscale (HADS-D). Each item is rated on a 4-point Likert scale. The total score for each subscale ranges from 0 to 21, with scores of 8–10 indicating mild anxiety or depression, 11–14 indicating moderate anxiety or depression, and 15–21 indicating severe anxiety or depression. Among Chinese cancer patients and their spousal caregivers, the Cronbach's α coefficients of both subscales were greater than 0.84.[26]

Data Collection

Prior to the study launch, the project team discussed data entry requirements and developed standardized guidelines to ensure consistency throughout the data collection process. To prevent measurement bias, intervention implementers did not participate in any form of data collection. For participants unable to complete questionnaires independently, trained data collectors provided necessary explanations and assistance. On-site verification was conducted immediately after questionnaire completion to ensure the completeness and accuracy of key information.

During data collection, researchers employed matched data from both BC patients and their spouse caregivers. Except for primary outcome measures (which were separate for patient and caregiver versions), identical scales were used for both partners. Data collection occurred at two time points: baseline (T0) and immediately post-intervention (T1).

Data Analysis

Statistical analyses were performed using SPSS 26.0. Continuous variables were expressed as mean ± standard deviation, and categorical variables were presented as frequencies or percentages. Between-group comparisons of baseline characteristics were conducted using the *t*-test, χ^2-test, or Fisher's exact test. A linear mixed model (LMM) was employed to evaluate the effect of the intervention on the total score of unmet needs.[27] Group (intervention and control), time (T0 and T1), and role (patient and spouse caregiver) were included as fixed effects, along with their interaction terms. To account for within-individual repeated measurements, study participants were treated as random effects. Secondary outcome measures (communication problems, quality of life, anxiety, and depression) were analyzed using multilevel modeling (MLM).[28] The independent variables comprised time, group, and role, with particular attention to the interaction effects of time × group and time × group × role in order to assess the effects of the intervention. Model parameters were estimated using the maximum likelihood method. The statistical significance level was set at $p< 0.05$ (two-tailed).

Ethical Considerations

This study was approved by the Medical Ethics Committee of the Affiliated Hospital of Jiangnan University (Approval number: LS2024335) and was conducted in accordance with the Declaration of Helsinki. The trial was registered with the Chinese Clinical Trial Registry (Registration number: ChiCTR2400091150). All participants voluntarily enrolled and provided written informed consent. Throughout the study, participants' preferences were fully respected, and they retained the right to withdraw at any time without penalty. All data were kept strictly confidential.

Results

Recruitment Rate and Retention Rate

This study recruited a total of 196 BC couples, with 122 couples ultimately meeting inclusion criteria and providing informed consent to participate (intervention group, n=61; control group, n=61), yielding a recruitment rate of 62.2%. During the intervention period, 11 couples from both groups were lost to follow-up (intervention group, n=5; control group, n=6). Ultimately, 56 couples in the intervention group and 55 couples in the control group completed the 6-week program and underwent post-intervention outcome assessments. Thus, the retention rate for this study was 91.0%. The detailed intervention study flow is illustrated in Figure 2.

Descriptive Characteristics

Baseline characteristics of the two study groups are shown in Table 1. The average age of the study subjects was approximately 50 years old. Most participants had primary or secondary education, no religious affiliation, and a household monthly income at the upper-middle level. The mean duration of marriage was (23.95±11.22) years in the intervention group and (25.43±9.03) years in the control group. Both groups reported mostly good marital quality and had children. 93.7% of patients had received their diagnosis within the past 12 months, with most cancers at stage II (45.05%). 64.9% of patients were undergoing postoperative chemotherapy. The majority of spousal caregivers reported good self-rated health (76.6%). There were no statistically significant differences in baseline characteristics between the intervention and control groups ($p>0.05$).

Analysis of Intervention Effects on Unmet Needs

For patients, the UN scores of the intervention and control groups at T0 were 80.89±10.36 and 79.75±7.36, respectively. From T0 to T1, the intervention group's score decreased by 9.29±8.69, while the control group's score decreased by 1.76 ±5.18. For spousal caregivers, the UN scores of the intervention and control groups at T0 were 56.93±7.81 and 56.47 ±5.64, respectively. From T0 to T1, the intervention group's score decreased by 5.57±5.95, whereas the control group's score decreased by 0.67±3.33. Detailed scores for patients and caregivers at different time points are presented in Table 2, and score changes are illustrated in Figure 3.

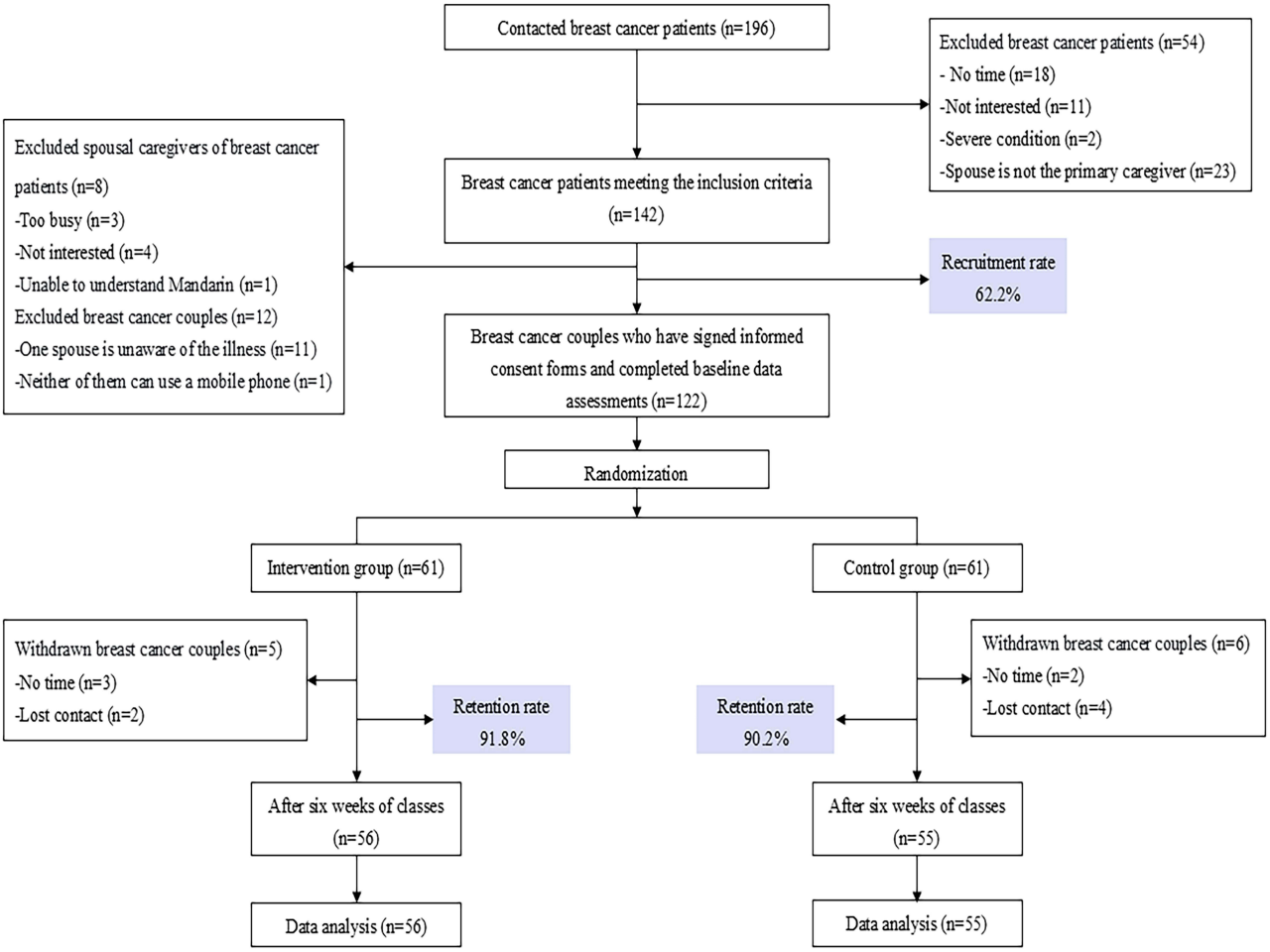

Figure 2 Flowchart of the intervention study.

Linear mixed model analysis revealed a significant group × time interaction for unmet needs (β=−4.90, SE=1.16, 95% CI −7.19 to −2.61, p<0.001), indicating that the intervention significantly reduced unmet needs over time compared with the control group. A significant time × role interaction was also observed (β=3.71, SE=1.56, 95% CI 1.44 to 5.99,

Table 1 Basic Characteristics of Participants and Comparisons Between Groups

Characteristics	BC Patients			Spousal Caregivers		
	Intervention Group (n=56)	Control Group (n=55)	t/χ^2/Fisher	Intervention Group (n=56)	Control Group (n=55)	t/χ^2/Fisher
Age Mean (SD)	48.29 (10.50)	49.76 (7.71)	0.40[a]	50.24 (10.20)	52.04 (7.61)	0.38[a]
Education level, n (%)			0.69[b]			0.85[b]
Junior high school and below	20 (35.7)	24 (43.6)		21 (37.5)	23 (41.8)	
High school or vocational school	19 (33.9)	17 (29.8)		20 (35.7)	17 (30.9)	
College and above	17 (30.4)	14 (25.5)		15 (26.8)	15 (27.3)	
Religious, n (%)			0.44[c]			0.29[c]
No	54 (96.4)	51 (92.7)		55 (98.2)	52 (94.5)	
Yes	2 (3.6)	4 (7.3)		1 (1.8)	3 (5.5)	

(*Continued*)

Table 1 (Continued).

Characteristics	BC Patients			Spousal Caregivers		
	Intervention Group (n=56)	Control Group (n=55)	t/χ^2/Fisher	Intervention Group (n=56)	Control Group (n=55)	t/χ^2/Fisher
Occupational status, n (%)			0.50[b]			0.66[b]
Employed	20 (35.7)	14 (25.5)		18 (32.1)	15 (27.3)	
Unemployed	15 (26.8)	17 (30.9)		15 (26.8)	19 (34.5)	
Retired	21 (37.5)	24 (43.6)		23 (41.1)	21 (38.2)	
Monthly income (Chinese Yuan), n (%)			0.83[b]			
<3000	6 (10.7)	8 (14.5)				
3000–5000	24 (42.9)	23 (41.8)				
>6000	26 (46.4)	24 (43.6)				
Medical Insurance, n (%)			0.79[c]			
Employee Medical Insurance	21 (37.5)	15 (27.3)				
Urban Resident Medical Insurance	20 (35.7)	18 (32.7)				
New Rural Cooperative Medical Scheme	14 (25.0)	20 (36.4)				
Non-local Medical Insurance	1 (1.8)	2 (3.6)				
Length of Marriage Mean (SD)	23.95 (11.22)	25.43 (9.03)	0.44[a]			
Marital Quality, n (%)			0.76[c]			
Good	39 (69.6)	36 (65.5)				
Average	17 (30.4)	18 (32.7)				
Poor	0 (0)	1 (1.8)				
Presence of Children, n (%)			0.68[c]			
No	4 (7.1)	2 (3.6)				
Yes	52 (92.9)	53 (96.3)				
Tumor stage, n (%)			0.89[c]			
I	16 (28.6)	13 (23.6)				
II	25 (44.6)	25 (45.5)				
III	14 (25.0)	16 (29.1)				
IV	1 (1.8)	1 (1.8)				
Duration of Illness, n (%)			0.60[c]			
<3 months	19 (33.9)	16 (29.1)				
3~6 months	20 (35.7)	16 (29.1)				
6~12 months	14 (25.0)	19 (34.5)				
1~3 years	1 (1.8)	2 (3.6)				
>3 years	2 (3.6)	2 (3.6)				

(*Continued*)

Table 1 (Continued).

Characteristics	BC Patients			Spousal Caregivers		
	Intervention Group (n=56)	Control Group (n=55)	t/χ^2/Fisher	Intervention Group (n=56)	Control Group (n=55)	t/χ^2/Fisher
Current Treatment Approach, n (%)			0.77[b]			
Surgery + Chemotherapy	35 (62.5)	37 (67.3)				
Surgery + Radiotherapy	6 (10.7)	5 (9.1)				
Surgery + Radiotherapy and Chemotherapy	7 (12.5)	8 (14.5)				
Other	8 (14.3)	5 (9.1)				
Health status, n (%)						0.79[c]
Good				44 (78.6)	41 (74.5)	
Average				11 (19.6)	12 (21.8)	
Poor				1 (1.8)	2 (3.6)	

Notes: [a]*t*-test; [b]Chi-square test; [c]Fisher's exact test.
Abbreviations: BC, breast cancer; SD, Standard Deviation.

Table 2 Baseline and Post-Intervention Scores of All Study Outcomes in the Intervention and Control Groups

Outcome	Group	Role	T0 Mean (SD)	T1 Mean (SD)
Unmet needs	Intervention	Patients	80.89 (10.36)	71.61 (8.72)
		Spousal Caregivers	56.93 (7.81)	51.36 (7.35)
	Control	Patients	79.75 (7.36)	77.98 (6.95)
		Spousal Caregivers	56.47 (5.64)	55.80 (4.83)
Communication issues	Intervention	Patients	7.66 (2.27)	5.05 (2.26)
		Spousal Caregivers	7.11 (2.37)	5.93 (2.34)
	Control	Patients	7.87 (2.27)	7.65 (2.25)
		Spousal Caregivers	6.89 (2.16)	6.91 (2.13)
Physical health	Interventional	Patients	40.66 (8.97)	42.50 (8.13)
		Spousal Caregivers	49.88 (6.51)	50.61 (6.68)
	Control	Patients	41.36 (6.66)	40.15 (6.79)
		Spousal Caregivers	48.65 (5.60)	47.47 (6.32)
Psychological health	Interventional	Patients	45.98 (6.86)	51.60 (6.36)
		Spousal Caregivers	47.34 (5.30)	50.57 (6.15)
	Control	Patients	46.71 (5.99)	45.98 (6.03)
		Spousal Caregivers	47.55 (4.26)	47.69 (4.59)

(*Continued*)

Table 2 (Continued).

Outcome	Group	Role	T0 Mean (SD)	T1 Mean (SD)
Anxiety	Interventional	Patients	6.57 (2.10)	4.91 (2.02)
		Spousal Caregivers	6.46 (2.23)	5.23 (2.28)
	Control	Patients	6.29 (2.55)	6.16 (2.28)
		Spousal Caregivers	6.62 (2.05)	6.75 (2.14)
Depression	Interventional	Patients	7.71 (2.87)	5.34 (2.08)
		Spousal Caregivers	7.54 (2.13)	5.38 (2.04)
	Control	Patients	7.82 (2.04)	7.24 (2.69)
		Spousal Caregivers	7.87 (2.25)	7.93 (2.05)

Notes: T0: baseline; T1: immediately after the intervention.
Abbreviation: SD, Standard Deviation.

p=0.004), suggesting different trajectories of unmet needs between patients and spousal caregivers. However, the group × time × role interaction was not statistically significant (β=−2.62, SE=1.64, 95% CI −5.86 to 0.61, p=0.111). The linear mixed model results are summarized in Table 3.

Analysis of Intervention Effects on Communication Problems

For patients, the communication problem scores at T0 were 7.66±2.27 and 7.87±2.27 in the intervention and control groups, respectively. From T0 to T1, the scores decreased by 2.61±2.02 in the intervention group and 0.22±1.38 in the control group. For spousal caregivers, the scores at T0 were 7.11±2.37 and 6.89±2.16 in the intervention and control groups, respectively. From T0 to T1, the scores decreased by 1.18±1.28 in the intervention group and increased by 0.02 ±0.91 in the control group. Detailed scores for patients and caregivers at different time points are presented in Table 2, and score changes are illustrated in Figure 4.

The MLM was used to evaluate the effects of the intervention on communication problems among patient–spouse dyads. The model included three fixed effects (time, time × group, and time × group × role), while individual participants and the dyadic relationship between patient and spouse were included as random effects. The results showed that when time was specified as a fixed effect, the intervention group exhibited significantly lower communication problem scores at T1 compared with T0, whereas no significant change was observed in the control group. When the fixed effect was time × group, BC couples in the intervention group reported fewer cancer-related communication problems than those in

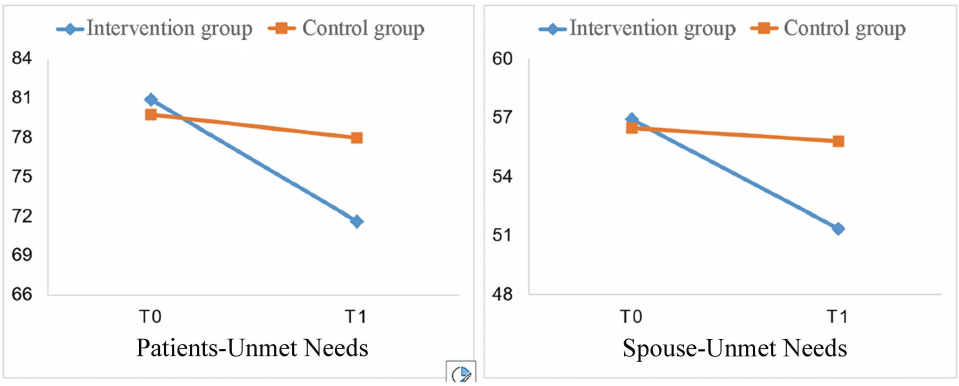

Figure 3 Changes in the scores for unmet need in the two groups.

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Table 3 Linear Mixed Model Analysis of the Effects of the Intervention on Unmet Needs

Fixed Effect	β	SE	95% CI	*p*
Group	4.44	1.35	(1.78, 7.10)	0.014
Time	5.57	0.82	(3.96, 7.18)	<0.001
Role	20.25	1.34	(17.60, 22.90)	<0.001
Group × Time	−4.90	1.16	(−7.19, −2.61)	<0.001
Group × Role	1.93	1.91	(−1.83, 5.69)	0.739
Time × Role	3.71	1.56	(1.44, 5.99)	0.004
Group × Time × Role	−2.62	1.64	(−5.86, 0.61)	0.111

Notes: Linear mixed models were used to examine the effects of time (T0 vs. T1), group (intervention vs. control), and role (patient vs. spousal caregiver) on unmet needs. Participant and couple were included as random effects in the model. T0 = baseline; T1 = post-intervention.
Abbreviations: β, regression coefficient; SE, standard error; CI, confidence interval.

the control group (B=−0.98, p=0.022). When the fixed effect was time × group × role, BC patients in the intervention group demonstrated greater improvement in communication than their spouse caregivers (B=−0.88, p=0.040). Detailed MLM results are presented in Table 4.

Analysis of Intervention Effects on Quality of Life

For patients, the physical health scores of the intervention and control groups at T0 were 40.66±8.97 and 41.36±6.66, respectively. From T0 to T1, the intervention group's score increased by 1.91±11.01, whereas the control group's score decreased by 1.22±4.79. For spousal caregivers, the physical health scores of the intervention and control groups at T0 were 49.88±6.51 and 48.65±5.60, respectively. From T0 to T1, the intervention group's score increased by 0.73±5.91, while the control group's score decreased by 1.18±4.90. Detailed scores for patients and caregivers at different time points are presented in Table 2. The changes in scores are shown in Figure 5.

Regarding psychological health, patients in the intervention and control groups had scores of 45.98±6.86 and 46.71 ±5.99 at T0, respectively. From T0 to T1, the intervention group's score increased by 5.68±5.46, whereas the control group's score decreased by 0.72±3.49.

For spousal caregivers, the psychological health scores at T0 were 47.34±5.30 for the intervention group and 47.55±4.26 for the control group. From T0 to T1, the intervention group's score increased by 3.23±6.44, while the control group's score

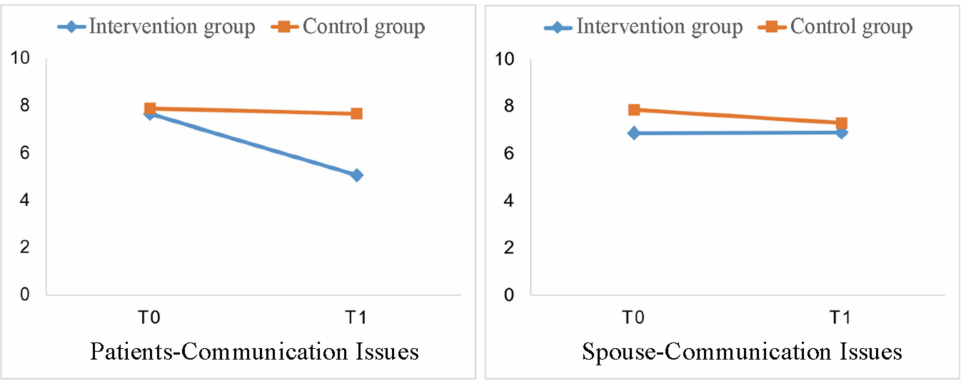

Figure 4 Changes in the scores for mutual communication in the two groups.

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Table 4 Results of the MLM Analysis of Mutual Communication

Variables	Parameter	*B*	*SE*	*t*	*P*	95% CI
Communication issues	Intercept	6.91	0.30	22.89	<0.001	(6.31, 7.50)
	Time 0	−0.02	0.19	−0.09	0.926	(−0.40, 0.37)
	Time 1	0				
	Time 0 × Group 1	0.22	0.42	0.51	0.611	(−0.62, 1.05)
	Time 0 × Group 2	0				
	Time 1 × Group 1	−0.98	0.42	−2.31	0.022	(−1.82, −0.14)
	Time 1 × Group 2	0				
	Time 0 × Group 1 × Role 1	0.55	0.42	1.31	0.192	(−0.28, 1.39)
	Time 0 × Group 1 × Role 2	0				
	Time 1 × Group 1 × Role 1	−0.88	0.42	−2.07	0.040	(−1.71, −0.04)
	Time 1 × Group 1 × Role 2	0				
	Time 0 × Group 2 × Role 1	0.98	0.43	2.30	0.022	(0.14, 1.82)
	Time 0 × Group 2 × Role 2	0				
	Time 1 × Group 2 × Role 1	0.75	0.43	1.75	0.082	(−0.09, 1.59)
	Time 1 × Group 2 × Role 2	0				

Notes: Time: 0=T0, 1=T1; Group: 1= Intervention Group, 2=Control Group; Role: 1=Patients, 2= Spousal Caregivers.
Abbreviations: B, regression coefficient; SE, standard error; CI, confidence interval.

increased slightly by 0.14±2.75. Scores at different time points for patients and spouse caregivers in the intervention and control groups are shown in Table 2, with changes depicted in Figure 6.

The MLM was applied to evaluate the effects of the intervention on quality of life among patient–spousal caregiver dyads. The model included three fixed effects (time, time × group, and time × group × role), while individual participants and the dyadic relationship between patient and spouse were included as random effects. The results indicated that, with time as a fixed effect, the intervention group showed significantly higher scores in physical and psychological health at T1 compared to T0, whereas no significant changes were observed in the control group. When time × group was treated as a fixed effect, BC dyads in the intervention group demonstrated better physical and psychological health compared to those in the control group (B=3.13, p=0.018; B=2.88, p=0.008). When time × group × role was specified as a fixed effect,

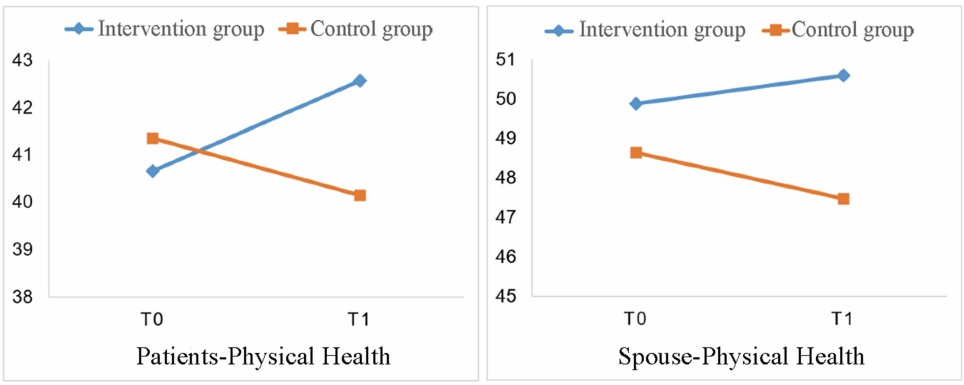

Figure 5 Changes in the scores for quality of life-physical health in the two groups.

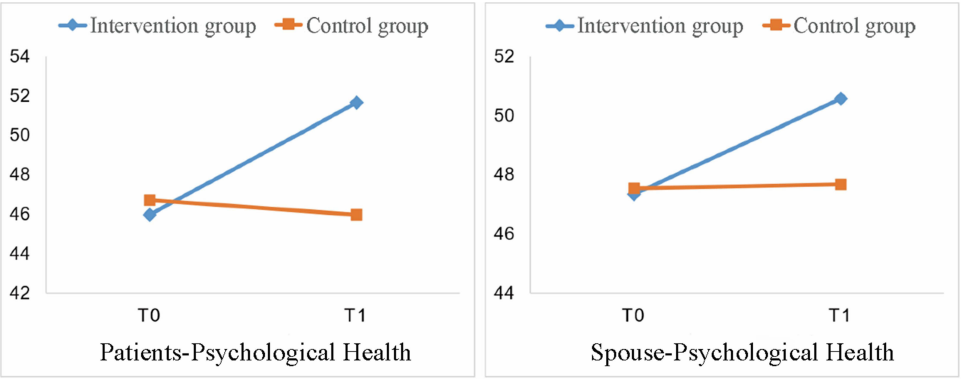

Figure 6 Changes in the scores for quality of life-mental health in the two groups.

patients in the intervention group exhibited significantly greater improvements in physical health compared with their spousal caregivers (B=−8.04, p<0.001), while role had no significant effect on psychological health. Detailed MLM results are presented in Table 5.

Table 5 Results of the MLM Analysis of Quality of Life

Variables	Parameter	*B*	*SE*	*t*	*P*	95% CI
Physical health	Intercept	47.47	0.94	50.49	<0.001	(45.62, 49.32)
	Time 0	1.18	0.93	1.27	0.204	(−0.65, 3.01)
	Time 1	0				
	Time 0 × Group 1	1.22	1.32	0.92	0.357	(−1.38, 3.82)
	Time 0 × Group 2	0				
	Time 1 × Group 1	3.13	1.32	2.37	0.018	(0.53, 5.74)
	Time 1 × Group 2	0				
	Time 0 × Group 1 × Role 1	−9.21	1.27	−7.28	<0.001	(−11.71, −6.72)
	Time 0 × Group 1 × Role 2	0				
	Time 1 × Group 1 × Role 1	−8.04	1.27	−6.35	<0.001	(−10.53. −5.54)
	Time 1 × Group 1 × Role 2	0				
	Time 0 × Group 2 × Role 1	−7.29	1.28	−5.71	<0.001	(−9.81, −4.77)
	Time 0 × Group 2 × Role 2	0				
	Time 1 × Group 2 × Role 1	−7.33	1.28	−5.74	<0.001	(−9.84, −4.81)
	Time 1 × Group 2 × Role 2	0				
Psychological Health	Intercept	47.69	0.77	61.99	<0.001	(46.18, 49.20)
	Time 0	−0.15	0.64	−0.23	0.820	(−1.41, 1.11)
	Time 1	0				
	Time 0 × Group 1	−0.21	1.08	−0.19	0.849	(−2.34, 1.93)
	Time 0 × Group 2	0				

(*Continued*)

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Table 5 (Continued).

Variables	Parameter	*B*	*SE*	*t*	*P*	95% CI
	Time 1 × Group 1	2.88	1.08	2.66	0.008	(0.75, 5.01)
	Time 1 × Group 2	0				
	Time 0 × Group 1 × Role 1	−1.36	1.0	−1.34	0.183	(−3.36, 0.65)
	Time 0 × Group 1 × Role 2	0				
	Time 1 × Group 1 × Role 1	1.09	1.01	1.07	0.284	(−0.91, 3.09)
	Time 1 × Group 1 × Role 2	0				
	Time 0 × Group 2 × Role 1	−0.84	1.02	−0.82	0.415	(−2.86, 1.18)
	Time 0 × Group 2 × Role 2	0				
	Time 1 × Group 2 × Role 1	−1.71	1.02	−1.67	0.097	(−3.73, 0.31)
	Time 1 × Group 2 × Role 2	0				

Notes: Time: 0=T0, 1=T1; Group: 1= Intervention Group, 2=Control Group; Role: 1=Patients, 2= Spousal Caregivers.
Abbreviations: B, regression coefficient; SE, standard error; CI, confidence interval.

Analysis of Intervention Effects on Anxiety and Depression

For patients, the anxiety scores at T0 were 6.57±2.10 and 6.29±2.55 in the intervention and control groups, respectively. From T0 to T1, the scores decreased by 1.66±2.14 in the intervention group and 0.13±1.61 in the control group. For spousal caregivers, the anxiety scores at T0 were 6.46±2.23 and 6.62±2.05 in the intervention and control groups, respectively. From T0 to T1, the scores decreased by 1.75±2.48 in the intervention group and increased by 0.13±1.78 in the control group. Detailed scores for patients and caregivers at different time points are presented in Table 2. The changes in scores are shown in Figure 7.

For patients, the depression scores at T0 were 7.71±2.87 and 7.82±2.04 in the intervention and control groups, respectively. From T0 to T1, the scores decreased by 2.38±2.33 in the intervention group and 0.58±1.95 in the control group. For spousal caregivers, the depression scores at T0 were 7.54±2.13 and 7.87±2.25 in the intervention and control groups, respectively. From T0 to T1, the scores decreased by 2.16±2.56 in the intervention group and increased by 0.05 ±1.38 in the control group. Scores at different time points for patients and spousal caregivers in the intervention and control groups are presented in Table 2, with changes illustrated in Figure 8.

The MLM was used to evaluate the improvement in anxiety and depression among patient-spouse caregivers in both groups following the intervention. The model included three fixed effects (time, time × group, and time × group × role),

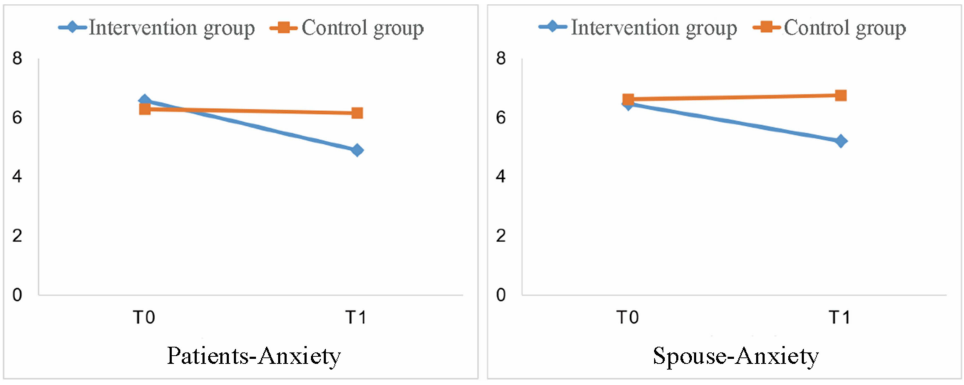

Figure 7 Changes in the scores for quality of anxiety in the two group.

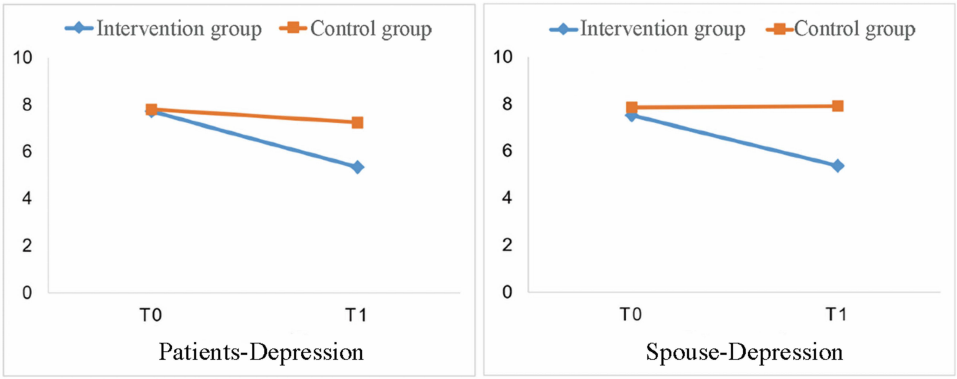

Figure 8 Changes in the scores for depression in the two groups.

while individual participants and the dyadic relationship between patient and spouse were included as random effects. The results showed that, with time as a fixed effect, the T1 anxiety and depression scores in the intervention group were significantly lower than those at T0, whereas no significant differences were observed in the control group. When time × group was included as a fixed effect, the intervention group demonstrated significantly lower anxiety and depression levels compared with the control group (B=−1.51, P<0.001; B=−2.55, P<0.001). The role factor showed no significant effects on anxiety or depression in the MLM analysis. The detailed results of the MLM model are presented in Table 6.

Table 6 Results of the MLM Analysis of Anxiety and Depression

Variables	Parameter	*B*	*SE*	*t*	*P*	95% CI
Anxiety	Intercept	6.75	0.29	22.92	<0.001	(6.17, 7.32)
	Time 0	−0.13	0.27	−0.47	0.640	(−0.66, 0.41)
	Time 1	0				
	Time 0 × Group 1	0.36	0.41	0.88	0.380	(−0.45, 1.18)
	Time 0 × Group 2	0				
	Time 1 × Group 1	−1.51	0.41	−3.65	<0.001	(−2.33, −0.70)
	Time 1 × Group 2	0				
	Time 0 × Group 1 × Role 1	−0.41	0.39	−1.05	0.295	(−1.18, 0.36)
	Time 0 × Group 1 × Role 2	0				
	Time 1 × Group 1 × Role 1	−0.32	0.39	−0.82	0.412	(−1.09, 0.45)
	Time 1 × Group 1 × Role 2	0				
	Time 0 × Group 2 × Role 1	−0.33	0.39	−0.83	0.408	(−1.11, 0.45)
	Time 0 × Group 2 × Role 2	0				
	Time 1 × Group 2 × Role 1	−0.58	0.39	−1.48	0.142	(−1.36, 0.20)
	Time 1 × Group 2 × Role 2	0				

(*Continued*)

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Table 6 (Continued).

Variables	Parameter	*B*	*SE*	*t*	*P*	95% CI
Depression	Intercept	7.93	0.31	25.93	<0.001	(7.33, 8.53)
	Time 0	−0.05	0.28	−0.19	0.846	(−0.61, 0.50)
	Time 1	0				
	Time 0 × Group 1	−0.34	0.43	−0.78	0.434	(−1.18, 0.51)
	Time 0 × Group 2	0				
	Time 1 × Group 1	−2.55	0.43	−5.93	<0.001	(−3.40, −1.71)
	Time 1 × Group 2	0				
	Time 0 × Group 1 × Role 1	0.18	0.39	0.46	0.648	(−0.59, 0.95)
	Time 0 × Group 1 × Role 2	0				
	Time 1 × Group 1 × Role 1	−0.04	0.39	−0.09	0.927	(−0.81, 0.74)
	Time 1 × Group 1 × Role 2	0				
	Time 0 × Group 2 × Role 1	−0.05	0.39	−0.14	0.89	(−0.83, 0.72)
	Time 0 × Group 2 × Role 2	0				
	Time 1 × Group 2 × Role 1	−0.69	0.39	−1.75	0.081	(−1.47, 0.09)
	Time 1 × Group 2 × Role 2	0				

Notes: Time: 0=T0, 1=T1; Group: 1= Intervention Group, 2=Control Group; Role: 1=Patients, 2= Spousal Caregivers.
Abbreviations: B, regression coefficient; SE, standard error; CI, confidence interval.

Discussion

Research findings indicate that compared to the control group of BC patients and their spouse caregivers, couples who participated in the six-week UN supportive intervention program demonstrated significantly reduced levels of unmet needs, communication barriers, anxiety, and depression at the conclusion of the intervention (T1). Additionally, they exhibited higher levels of physical and psychological well-being.

The ERG-SCNF theory–based supportive intervention for UN effectively reduced unmet needs among BC patient–spouse dyads. Pooled data analysis showed that, following the UN-based supportive intervention, total unmet needs scores were significantly lower in both BC patients and their spouse caregivers in the intervention group compared with the control group. This finding is consistent with the results reported by Paterson et al in an intervention study involving prostate cancer patients and their spousal caregivers.[29] First, guided by the ERG-SCNF theoretical framework, the intervention was developed through qualitative interviews, literature review, and expert consultation, ensuring both theoretical grounding and relevance to the multidimensional needs of BC couples during disease coping.[30] Second, the intervention adopted a dyadic perspective that addressed both interaction patterns and shared coping capacity within the patient–spouse caregiver dyad. Previous studies have shown that dyadic coping is closely associated with unmet needs and psychosocial adjustment among cancer dyads.[31] Third, the intervention employed a hybrid delivery model combining online and face-to-face approaches, which improved both engagement and accessibility. Face-to-face interactions facilitated trust and participation, whereas online platforms provided flexible and continuous informational support.[32,33] In addition, structured health education, regular follow-up, and individualized feedback helped reduce illness-related uncertainty and promote adaptive coping, thereby helping address unmet supportive care needs among both patients and their spousal caregivers.[34]

The ERG-SCNF theory–based supportive intervention for UN improved communication problems among BC patient–spouse dyads. The MLM analysis indicated that BC patients and their spouse caregivers who received the intervention showed significant improvements in communication issues, whereas the control group showed limited improvement. This finding is consistent with the study by Fergus et al[35] In addition, Manne et al reported that communication interventions can promote self-disclosure and the perception of partner responses, thereby improving communication quality in cancer couples.[36] Cancer couples often avoid expressing concerns, needs, or fears due to "protective buffering," which can hinder effective communication.[37] In the present study, structured communication skills training, role-awareness guidance, and emotional expression exercises were integrated into the intervention, enhancing mutual understanding and support between spouses and reducing anxiety and emotional burden associated with ineffective communication.[38–40] Moreover, the intervention was tailored to the Chinese cultural context, facilitating acceptability and improvements in dyadic communication.

The ERG-SCNF theory–based supportive intervention for UN improved the quality of life (QoL) of BC patient–spouse dyads. The results indicated that the intervention group demonstrated marked improvements in physical health, whereas no similar positive changes were observed in the control group. This effect may be attributed to the intervention providing strategies for managing treatment-related side effects, medication guidance, postoperative rehabilitation training, and individualized gentle exercise programs, which enhanced patients' self-care abilities and physical functioning. This synergistic intervention approach is consistent with previous systematic reviews of dyadic interventions for cancer couples, highlighting the effectiveness of structured exercise and rehabilitation in promoting physical health.[41] At the psychological level, the intervention focused on emotion regulation and the reconstruction of life meaning. Mindfulness meditation, deep breathing, and progressive muscle relaxation exercises helped dyads alleviate negative emotions and enhance psychological resilience. The "life meaning exploration and value reconstruction" module, implemented through family discussions and case sharing, fostered patients' hope and confidence for the future. The results indicated that the intervention group demonstrated significant improvements in psychological well-being, which complemented the positive changes observed at the physiological level, resulting in an overall enhancement of quality of life.

The ERG-SCNF theory–based supportive intervention for UN reduced anxiety and depression levels among BC patient–spouse dyads. The intervention employed multiple emotion regulation techniques, including emotion recognition training, breathing exercises, and sound meditation, providing both patients and spouses with effective coping strategies. Combined with disease education and peer experience sharing, the intervention helped dyads establish positive expectations and enhance self-regulation capacity. Partner-assisted emotional disclosure further facilitated emotional release, mutual support, and improved communication within the couple. As noted by Sella et al, higher levels of patient self-disclosure are inversely associated with partner anxiety and depression, emphasizing the central role of emotional support in cancer care.[42] In contrast, anxiety and depression scores among caregivers in the control group slightly increased, suggesting that, in the absence of structured intervention, the ongoing caregiving burden may exacerbate psychological distress.[43] These findings underscore the importance of emotion management for cancer couples and support the implementation of dyadic psychological interventions, which, through joint participation and mutual support, can more effectively alleviate the psychological impact of the disease.

The research team specifically examined the impact of "role" (patient/spouse caregiver) on intervention outcomes during data analysis. Findings revealed that breast cancer patients demonstrated significantly greater improvement in communication issues post-intervention compared to spouse caregivers. This disparity may stem from gender roles and societal expectations, where women are often encouraged to express emotions more openly, while men are typically expected to remain strong and suppress emotional expression.[44] Consequently, female patients may be more inclined to adopt diverse communication methods to express personal feelings and needs during the intervention, thereby promoting communication improvement. In contrast, males may be constrained by traditional gender roles when expressing emotions, leading to relatively weaker communication outcomes. Simultaneously, BC patients also demonstrated significantly greater improvement in physical health compared to spouse caregivers following the intervention. This result may stem from patients having lower baseline physical health levels, making the intervention's direct impact on their physical health more pronounced.[45] Furthermore, patients experience greater physical fluctuations and emotional

volatility during disease treatment, making the intervention's impact on their physical health more pronounced. In contrast, spouse caregivers may neglect their own health needs while caring for patients, resulting in relatively smaller improvements in their health outcomes.

Although this study achieved its intended objectives regarding supportive interventions, several limitations remain. First, since most BC couples in the study had relatively good relationship quality, the effectiveness of the UN supportive intervention program for couples with average or poor relationship quality requires further validation. Second, this study assessed only short-term outcomes post-intervention, failing to fully capture the long-term stability and dynamic changes of intervention effects. Future research should extend follow-up periods and increase assessment points to observe sustained effects and potential need for re-intervention. Additionally, the small sample size and limited scope of this randomized controlled trial—conducted solely at a tertiary hospital in Wuxi City—restricts the generalizability of its findings. Future studies should adopt a multicenter, large-sample design to test the applicability of the intervention across diverse cultural and socioeconomic contexts.

Conclusion

The supportive care intervention targeting unmet needs among BC patient–spousal caregiver dyads, developed based on the ERG–SCNF theoretical framework, improved unmet needs, communication problems, physical health, psychological health, and levels of anxiety and depression in both partners. Future research is warranted to further examine the effectiveness of this intervention in couples with other types of cancer or in dyads with moderate or lower relationship quality, thereby providing additional evidence for the development of more scientifically grounded and effective intervention strategies.

Data Sharing Statement

Upon reasonable request, communicating the correspondence author (Kai Jiang) may present data in favor of the results of this research.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that there are no financial disclosures or other conflicts of interest in this study.

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