Randomized Clinical Trial of a Family Intervention for Prostate Cancer Patients and Their Spouses

Laurel L. Northouse, PhD, RN[1]
Darlene W. Mood, PhD[2,3]
Ann Schafenacker, RN, MSN[1]
James E. Montie, MD[4]
Howard M. Sandler, MD[4,5]
Jeffrey D. Forman, MD[3,6]
Maha Hussain, MD[4,7]
Kenneth J. Pienta, MD[4,7]
David C. Smith, MD[4,7]
Trace Kershaw, PhD[8]

[1] School of Nursing, University of Michigan, Ann Arbor, Michigan.

[2] College of Nursing, Wayne State University, Detroit, Michigan.

[3] Karmanos Cancer Center, Detroit, Michigan.

[4] Department of Urology, University of Michigan, Ann Arbor, Michigan.

[5] Department of Radiation Oncology, University of Michigan, Ann Arbor, Michigan.

[6] Department of Radiation Oncology, Wayne State University, Detroit, Michigan.

[7] Department of Internal Medicine, University of Michigan, Ann Arbor, Michigan.

[8] School of Public Health, Yale University, New Haven, Connecticut.

BACKGROUND. Few intervention studies have been conducted to help couples manage the effects of prostate cancer and maintain their quality of life. The objective of this study was to determine whether a family-based intervention could improve appraisal variables (appraisal of illness or caregiving, uncertainty, hopelessness), coping resources (coping strategies, self-efficacy, communication), symptom distress, and quality of life in men with prostate cancer and their spouses.

METHODS. For this clinical trial, 263 patient-spouse dyads were stratified by research site, phase of illness, and treatment; then, they were randomized to the control group (standard care) or the experimental group (standard care plus a 5-session family intervention). The intervention targeted couples' communication, hope, coping, uncertainty, and symptom management. The final sample consisted of 235 couples: 123 couples in the control group and 112 couples in the experimental group. Data collection occurred at baseline before randomization and at 4 months, 8 months, and 12 months.

RESULTS. At 4-month follow-up, intervention patients reported less uncertainty and better communication with spouses than control patients, but they reported no other effects. Intervention spouses reported higher quality of life, more self-efficacy, better communication, and less negative appraisal of caregiving, uncertainty, hopelessness, and symptom distress at 4 months compared with controls, and some effects were sustained to 8 months and 12 months.

CONCLUSIONS. Men with prostate cancer and their spouses reported positive outcomes from a family intervention that offered them information and support. Programs of care need to be extended to spouses who likely will experience multiple benefits from intervention. *Cancer* 2007;110:2809–18. © *2007 American Cancer Society.*

KEYWORDS: prostate cancer, family, quality of life, randomized clinical trial.

Prostate cancer is the most common cancer among men and is accompanied by serious treatment-related side effects, such as urinary incontinence and erectile dysfunction. These symptoms persist over time and can have a negative effect on the quality of life (QOL) of both men and their spouses.[1] Patients with prostate cancer often rely exclusively on their spouses for support and seldom discuss their concerns with others, possibly because of the intimate nature of the problems.[2] Consequently, the role of primary caregiver can be stressful for spouses. Several investigators have observed that spouses of men with prostate cancer report significantly more emotional distress than their husbands.[1,3] Spouses' higher distress may be related to their limited support from others, communication problems with partners, high uncertainty, and lower caregiver self-efficacy to manage the effects of the illness.[4]

Despite the serious problems that prostate cancer creates for patients and their spouses, there are surprisingly few intervention programs to help couples manage the effects of illness and maintain their QOL.[3,5] Prior randomized clinical trials (RCTs) have reported primarily on patient outcomes,[6–10] and only a few studies have reported spouse outcomes.[3,5,11] In addition, most behavioral interventions have been conducted during the newly diagnosed phase of prostate cancer,[6–10] but there are no intervention studies in the biochemical recurrence and advanced phases. Some men with prostate cancer are at greater risk of developing more distress than others, yet few studies have assessed patients' risk for distress to determine who is in need of psychosocial interventions.

Investigators have tested a variety of intervention formats (eg, computer-based, telephone, group) with some positive effects on patient outcomes, such as improved sexual function[7,10] or urinary control,[9] better cognitive reframing and problem solving,[9] more active decision-making,[6] and better mental health (eg, less anxiety, depression, or worry).[6–8,10] However, most intervention effects have been obtained at short-term follow-up, with only a few effects sustained over time.

To our knowledge, only 3 RCTs published to date have reported spouse outcomes.[3,5,11] A single, presurgical intervention session was offered to couples to enhance communication within the couple and with the medical team,[5] a comprehensive homecare intervention was offered to couples,[11] and a group psychoeducational intervention was offered to spouses only.[3] Spouses in the intervention arms of these studies reported less general stress,[5] more appreciation for life, personal strength, spiritual growth, less denial,[3] and more caregiver preparedness (on qualitative reports)[11] after the intervention than spouses in the control groups.

Although prior RCTs with prostate cancer patients and their spouses have laid important groundwork, more trials are needed to examine patient and spouse outcomes across the phases of illness. The objective of this study was to determine whether a family-based intervention could improve appraisal variables (appraisal of illness or caregiving, uncertainty, hopelessness), coping resources (coping strategies, self-efficacy, communication), symptom distress (general and prostate-specific), and QOL in patients and their spouses during 3 phases of prostate cancer (newly diagnosed, biochemical recurrence, and advanced). A stress-coping framework, which was adapted from the work of Lazarus and Folkman,[12] guided this study and the selection of variables. We hypothesized that couples who received the family intervention (FOCUS Program) would report fewer negative outcomes on appraisal variables, more positive outcomes on coping resources, and higher QOL than couples in the control group. We also examined 2 potential moderators—phase of prostate cancer and risk for distress—to determine whether either moderator created a differential effect of the intervention on patient or spouse outcomes.

MATERIALS AND METHODS
Design
An RCT with follow-up assessments at 4 months, 8 months, and 12 months was used to examine the effects of a family-based intervention on study outcomes of patients and their spouses/partners. Detailed information regarding sample accrual and retention[13] and on the baseline characteristics of participants[4] have been described previously. For this report, we examined the effects of the intervention on patient and spouse outcomes at initial follow-up (4 months) and at long-term follow-up (8 months and 12 months).

Sample
Patients were eligible if they were in 1 of 3 phases of prostate cancer (ie, newly diagnosed, biochemical recurrence, or advanced). We sought a cohort of patients and spouses in each phase who were facing either a new diagnosis, new biochemical recurrence, or new metastases or progression of advanced disease, ie, dyads that were considered more likely to benefit from the intervention. For each phase, there was a 2-month period of eligibility: 1) newly diagnosed, after the completion of primary treatment; 2) biochemical recurrence after 2 consecutive rises in their PSA; and 3) advanced, after diagnosis or progression of metastatic disease. Other patient criteria included age ≥ 30 years, a life expectancy ≥ 12 months, a spouse or live-in partner; and residence within 75 miles of participating cancer centers. Patients with second primary cancers were excluded.

Spouses/partners were eligible if they were aged ≥ 21 years and were identified by patients as their primary caregiver (ie, provider of emotional and/or physical care). Couples were excluded if spouses had been diagnosed with cancer within the prior year or were receiving cancer treatment.

Procedures
Eligible participants were identified by staff in surgery, radiation, and medical oncology clinics at 3

research sites. Potential participants were contacted by research staff and, if they agreed to be enrolled, were scheduled for a home visit to complete consent forms approved by institutional review boards and to collect baseline data. Patients were stratified by treatment centers (3 sites), phase of illness (3 phases), and type of treatment; then, they were randomized with spouses into control or experimental treatment arms. Data collection nurses who were blinded to group assignment collected data from couples at baseline and at 4 months, 8 months, and 12 months. A separate team of masters-prepared nurses delivered the intervention. Only assessments that were completed by both patient and spouse were included in this analysis.

Treatment Conditions
Control condition
Couples in the control group received standard clinic care at their cancer center that addressed primarily diagnosis and treatment of patients' disease. Although the centers offered some support groups, no specific psychosocial resources were targeted for couples facing prostate cancer.

Experimental condition
Couples in the experimental group received standard clinic care plus a family-based intervention called the FOCUS Program, a supportive-educative intervention that was tested initially with breast cancer patients and their family caregivers[14,15] and was modified to address the needs of prostate cancer patients and their spouses. The program consists of 3 90-minute home visits and 2 30-minute telephone sessions spaced 2 weeks apart and delivered between baseline and 4 months.

The content consists of 5 core areas represented by the acronym FOCUS: *F*amily involvement, *O*ptimistic attitude, *C*oping effectiveness, *U*ncertainty reduction, and *S*ymptom management. Interventions that pertained to *family involvement* encouraged couples to work as a team, communicate openly about the illness, and provide one another with support. *Optimistic attitude* interventions helped couples maintain hope and focus on achievable, short-term goals. *Coping effectiveness* interventions emphasized techniques to reduce stress, active coping strategies, and healthy lifestyle behaviors. *Uncertainty reduction* interventions taught couples how to obtain information and ways to live with uncertainty. *Symptom management* interventions included self-care strategies to manage symptoms both experienced. Although the program had core areas, the content also was *targeted* to the needs of

couples across the 3 phases of prostate cancer and *tailored* to the needs of individual couples within phases.

Intervention nurses were trained by the principal investigator (PI) and coinvestigators during a 40-hour training program, viewed a FOCUS intervention training video, and accompanied experienced intervention nurses on multiple in-home intervention sessions before they started their own caseloads. Several strategies were implemented to maintain treatment fidelity. Intervention nurses 1) completed a 21-page protocol checklist that outlined interventions for each session; 2) recorded the percent of time they spent on the FOCUS components in each session; 3) audiotaped randomly selected home visits, which were reviewed by the PI for consistency with protocol guidelines; and 4) provided case presentations to the PI and other intervention nurses at monthly, 2-hour staff meetings to ensure they were intervening consistently within and across cases.

An analysis of 30 randomly selected protocol checklists indicated that 98.3% of the interventions were documented as adhering to the manualized protocol. Review of audiotaped sessions indicated that the intervention was delivered with competence (eg, provided accurate information that was responsive to participants' concerns) and was consistent with protocol guidelines. Furthermore, the percent of time spent on FOCUS components was similar among all intervention nurses. These indicators suggested that treatment fidelity consistently was high.

Instruments
Established instruments were used to measure all study variables. Internal consistency reliabilities for each measure were assessed across all 4 administrations. The mean α reliability coefficients are listed in Tables 1 and 2.

Quality of life
A general QOL measure, the Medical Outcomes Study 12-item short form (MOS SF-12) (version 2),[16] and a cancer-specific measure, the general Functional Assessment of Cancer Treatment (FACT-G) (version 4),[17] were used to assess patients' and spouses' QOL. The MOS SF-12 yields summary scores for physical and mental QOL. The 27-item FACT-G assessed overall QOL. Because each individual reported on his or her own QOL, spouses' FACT-G required slight wording modifications. Patients also completed a prostate-specific QOL scale, the FACT-P.

TABLE 1
Comparisons Between Patients in the Intervention Group (FOCUS) and the Control Group, Controlling for Baseline Scores

Patient variable	α Mean*	4-Month follow-up				8-Month follow-up				12-Month follow-up			
		Mean (SD)				Mean (SD)				Mean (SD)			
		FOCUS group	Control group	Effect size	F [P]	FOCUS group	Control group	Effect size	F [P]	FOCUS group	Control group	Effect size	F [P]
Quality of life†													
SF Physical	.86	48.6 (6.7)	48.7 (6.5)	−.02	0.01 [.96]	43.3 (6.6)	43.6 (6.5)	−.05	0.06 [.80]	42.7 (6.5)	42.5 (6.4)	.03	0.02 [.88]
SF Mental	.87	52.4 (6.5)	51.9 (6.6)	.08	0.41 [.53]	53.4 (7.1)	53.8 (7.1)	−.06	0.16 [.69]	53.1 (7.1)	53.6 (7.1)	−.07	0.01 [.96]
FACT-G	.90	87.2 (10.6)	85.5 (10.3)	.16	2.67 [.10]	87 (10.8)	86.9 (10.6)	.01	0.02 [.89]	86.1 (10.9)	85.8 (10.7)	.03	0.09 [.77]
Appraisal variables‡													
Appraisal of illness	.96	2.16 (0.74)	2.23 (0.71)	−.10	1.51 [.22]	2.20 (0.76)	2.22 (0.72)	−.03	0.06 [.81]	2.23 (0.76)	2.20 (0.73)	.04	0.12 [.74]
Uncertainty	.92	56.9 (14.2)	60 (13.5)	−.22	4.50 [.03]§	57.7 (14.6)	58.5 (13.5)	−.06	0.33 [.57]	57.5 (14.7)	57.4 (13.2)	.01	0.01 [.97]
Hopelessness	.88	2.23 (2.4)	2.69 (3.1)	−.17	3.22 [.07]	2.62 (2.7)	2.67 (3.1)	−.02	0.02 [.88]	2.72 (2.7)	2.57 (3.1)	.01	0.19 [.67]
Coping resources													
Self-efficacy†	.97	146.1 (19)	146 (20.2)	.01	0.01 [.98]	146.2 (19.4)	147.2 (20.5)	−.05	0.17 [.68]	144.7 (19.6)	146.1 (20.6)	−.07	0.32 [.57]
Communication†	.91	3.80 (0.46)	3.69 (0.52)	.22	4.79 [.03]§	3.74 (0.48)	3.79 (0.50)	−.10	0.92 [.34]	3.72 (0.48)	3.71 (0.51)	.01	0.04 [.85]
Active coping†	.80	31.3 (5.7)	31 (6)	.05	0.16 [.69]	31.8 (5.7)	31.3 (6.1)	.08	0.91 [.34]	32.1 (5.5)	30.9 (6)	.20	2.23 [.14]
Avoidant coping‡	.60	14.4 (2.8)	14.2 (2.7)	.07	0.40 [.53]	31.8 (2.8)	31.3 (2.7)	.18	2.19 [.14]	14.9 (2.8)	14.3 (2.7)	.20	2.13 [.15]
Symptoms													
Symptom distress‡	.82	5.99 (3.6)	6.19 (3.6)	−.06	0.28 [.60]	6.41 (3.7)	6.13 (3.7)	.08	0.57 [.45]	6.24 (3.8)	6.02 (3.7)	.06	0.29 [.59]
Urinary†	.84	86.9 (12.7)	81.6 (13.8)	.19	2.86 [.09]	84.4 (12.5)	83.1 (13.7)	.10	1.02 [.32]	84.5 (12.5)	83.9 (13.6)	.05	0.19 [.67]
Bowel†	.85	89.5 (7)	90.3 (8.4)	−.10	0.33 [.57]	90.5 (7)	89.9 (8.4)	.08	0.28 [.60]	89.6 (7.4)	90.5 (8)	−.12	0.59 [.44]
Sexual†	.92	28.5 (21.4)	29.3 (20.9)	−.04	0.13 [.72]	31.7 (21.6)	29.2 (21.1)	.12	1.41 [.24]	30.4 (21.7)	31.3 (21.1)	−.04	0.14 [.71]
Hormone†	.77	83.7 (9.9)	83.8 (10.4)	.01	0.01 [.95]	85.5 (9.9)	85.4 (10.3)	.01	0.01 [.97]	83.9 (10)	85.2 (10.3)	−.13	0.85 [.36]

SD indicates standard deviation; SF Physical, Physical subscale from the Medical Outcomes Study 12-item short form (MOS SF-12); SF Mental, Mental subscale from the MOS SF-12; FACT-G, Functional Assessment of Cancer Treatment-General.

* The average reliability coefficient α across all administrations.

† Higher scores indicate more positive results; ie, higher quality of life, more self-efficacy, more communication with spouse, more use of active coping strategies, and better prostate-specific symptom outcomes.

‡ Higher scores indicate more negative results; ie, more negative appraisal of the illness, more uncertainty, more hopelessness, more use of avoidant coping strategies, and more symptom distress.

§ $P \leq .05$.

TABLE 2
Comparisons Between Spouses in the Intervention Group (FOCUS) and the Control Group, Controlling for Baseline Scores

Spouse variable	α Mean*	4-Month follow-up				8-Month follow-up				12-Month follow-up			
		Mean (SD)				Mean (SD)				Mean (SD)			
		FOCUS group	Control group	Effect size	F [P]	FOCUS group	Control group	Effect size	F [P]	FOCUS group	Control group	Effect size	F [P]
Quality of life†													
SF Physical	.84	50 (7.8)	50.3 (7.2)	−.04	0.19 [.67]	44.9 (7.2)	42.9 (7.1)	.28	5.83 [.02]‡	44.6 (7.2)	42.3 (7.2)	.32	7.99 [.005]§
SF Mental	.87	50.9 (7.5)	49 (7.5)	.25	4.89 [.03]‡	50.8 (7.7)	51.7 (7.7)	−.12	0.72 [.40]	51.5 (7.6)	52 (7.6)	−.07	0.22 [.76]
FACT-G	.92	86.5 (11.3)	83.5 (11.4)	.26	8.64 [.004]§	85.6 (11.5)	83.4 (11.9)	.19	3.67 [.06]	85.2 (11.6)	83.6 (11.9)	.14	1.77 [.18]
Appraisal variables‖													
Appraisal of caregiving	.88	2.29 (0.49)	2.44 (0.46)	−.32	10.21 [.002]§	2.33 (0.51)	2.41 (0.48)	−.16	1.92 [.17]	2.35 (0.51)	2.39 (0.49)	−.08	0.44 [.51]
Uncertainty	.92	59.5 (12.2)	63.1 (13.9)	−.28	7.04 [.009]§	59.5 (12.5)	62.2 (13.9)	−.22	3.76 [.05]‡	60.3 (12.5)	61.1 (13.9)	−.13	0.35 [.55]
Hopelessness	.79	2.47 (2.1)	3.07 (2.4)	−.27	4.49 [.03]‡	2.72 (2.2)	2.86 (2.4)	−.06	0.26 [.61]	2.71 (2.2)	3.06 (2.5)	−.15	1.40 [.25]
Coping resources													
Self-efficacy†	.97	144.1 (17.8)	138.8 (22.3)	.26	5.33 [.02]‡	141.7 (18.2)	136.7 (22.8)	.24	3.70 [.06]	143.8 (17.9)	137.8 (22.6)	.27	5.75 [.02]‡
Communication†	.92	3.74 (0.53)	3.57 (0.56)	.31	9.48 [.002]§	3.66 (0.54)	3.52 (0.56)	.25	6.34 [.01]‡	3.66 (0.54)	3.5 (0.56)	.29	7.03 [.009]§
Active coping†	.80	29.9 (5.7)	29 (5.5)	.16	2.03 [.16]	29.4 (5.8)	28.8 (5.6)	.11	0.70 [.40]	30.5 (5.5)	28.9 (6)	.28	5.49 [.02]‡
Avoidant coping‖	.61	14.4 (3.1)	15 (2.9)	−.20	2.13 [.15]	14.8 (2.8)	15.3 (2.7)	−.18	1.49 [.22]	14.9 (3.1)	14.9 (2.9)	.00	0.01 [.99]
Symptoms													
Symptom distress‖	.81	5.10 (3.4)	6.28 (3.6)	−.34	7.57 [.006]§	5.61 (3.7)	6.19 (3.7)	−.16	1.96 [.16]	5.70 (3.6)	6.04 (3.7)	−.09	0.67 [.42]
Urinary‖	NA	1.60 (0.70)	1.85 (0.78)	−.30	4.22 [.04]‡	1.53 (0.67)	1.81 (0.75)	−.40	6.96 [.009]§	1.62 (0.65)	1.75 (0.75)	−.18	1.31 [.25]
Bowel‖	NA	1.48 (0.60)	1.38 (0.54)	.18	1.49 [.22]	1.40 (0.63)	1.39 (0.57)	.02	0.01 [.94]	1.49 (0.63)	1.43 (0.56)	.14	0.27 [.60]
Sex‖	NA	2.74 (1.1)	2.77 (1.2)	−.03	0.05 [.83]	2.76 (1.1)	2.74 (1.1)	.02	0.01 [.93]	2.90 (1.1)	2.79 (1.1)	.10	0.37 [.54]
Hormone‖	NA	1.93 (0.83)	1.97 (0.81)	−.05	0.10 [.74]	1.97 (0.82)	1.94 (0.80)	.04	0.07 [.80]	1.99 (0.83)	1.99 (0.79)	.00	0.01 [.99]

SD indicates standard deviation; SF Physical, Physical subscale from the Medical Outcomes Study 12-item short form (MOS SF-12); SF Mental, Mental subscale from the MOS SF-12; FACT-G, Functional Assessment of Cancer Treatment-General; NA, not applicable.

* The average reliability coefficient α across all administrations.

† Higher scores indicate more positive results; ie, higher quality of life, more caregiver self-efficacy, more communication with patient, and more use of active coping strategies.

‡ $P \le .05$.

§ $P \le .01$

‖ Higher scores indicate more negative results; ie, more negative appraisal of caregiving, more uncertainty, more hopelessness, more use of avoidant coping strategies, more symptom distress, and more problems with patient's symptoms.

Appraisal variables

Appraisals of illness/caregiving were assessed with separate, 27-item Appraisal of Illness or Appraisal of Caregiving Scales.[18] These scales measure patients' level of threat associated with the illness and spouses' perception of caregiving. *Uncertainty* was assessed with the 28-item Mishel Uncertainty in Illness Scale,[19] and *hopelessness* was assessed with the 20-item Beck Hopelessness Scale.[20]

Coping resource variables

Coping strategies were assessed with the 28-item Brief Coping Orientations to Problems Experienced scale,[21] that was factor analyzed into active and avoidant coping dimensions. *Self-efficacy* was assessed with the 17-item Lewis Cancer Self-efficacy Scale, which measures confidence in managing stress and changes associated with cancer or treatments.[22] *Communication* about the illness was assessed with the 32-item Lewis Mutuality and Interpersonal Sensitivity Scale.[22]

Symptoms

General symptom distress was measured with the 16-item Symptom Scale of the Omega Screening Questionnaire (OSQ).[23] Both patients and spouses rated how much they were experiencing symptoms such as fatigue and sleeping problems. *Prostate-specific symptoms* were assessed with the 50-item Expanded Prostate Cancer Index Composite (EPIC), which measures patients' urinary, bowel, sexual, and hormone symptoms.[24] Spouses completed the 4-item spousal version of the EPIC, which assessed the extent to which husbands' prostate-specific symptoms created problems for spouses. Concurrent validity of the spouse EPIC was established by the significant correlations between patients' and spouses' scores on the scales (all $P < .001$).[4]

Risk for distress

The risk of developing future emotional distress was measured (at baseline only) with the 77-item OSQ, developed by Mood and Bickes[23] from the original Omega Clinical Screening Interview.[25,26] The OSQ assesses demographics, health history, current concerns, and symptom distress and yields a composite risk score that ranges from 0 to 23 (high risk, ≥ 9) with good reliability and validity.

Data Analysis

Chi-square analyses and Student *t* tests were conducted to assess any differences between the intervention and control groups at baseline. To assess the effectiveness of the intervention, random-effects regression analyses were conducted. Random-effects regression models use an iterative method that estimates a trajectory for each participant based on all available data for that participant augmented by data from the whole sample. These analyses have advantages over traditional analysis of variance models: They allow the use of all available data from all participants rather than dropping participants with missing data, and they incorporate serial correlations among observations over time, which results in less bias. To control for multiple tests, the α was reduced to $P \leq .01$ (test of significance). Values obtained between $P > .01$ and $P \leq .05$ were considered statistical trends. In addition, effect sizes were calculated for all comparisons (Tables 1, 2). Three a priori, planned comparisons were conducted comparing the intervention and control groups at 4-, 8-, and 12-month assessments and controlling for baseline scores.

RESULTS

Description of the Sample

During a 3-year period of recruitment, 429 patients were referred to the study from clinic staff. Of these referrals, 46 patient-spouse dyads did not meet all eligibility criteria, and 120 dyads refused study participation. Reasons for refusal varied but generally were because patients were too ill or because of competing priorities within the dyad. The remaining 263 dyads (68.7%) enrolled and completed baseline assessments.

Of the 263 enrolled dyads, 235 dyads (90%) completed the 4-month assessment, and 218 dyads (83%) completed all 3 follow-up assessments. The final sample for all analyses consisted of 235 dyads with at least 1 follow-up assessment (112 intervention dyads and 123 control dyads) (see Fig. 1). Comparing the intervention and control groups, there were no significant differences in the number of follow-up assessments, the number of participants lost to follow-up, the number of participants who completed all follow-up assessments, or participants lost to other reasons (all $P > .10$). Among the 45 dyads that did not complete the study, reasons included patient death (15 dyads; 33.3%), declined intervention (9 dyads; 20%), too busy (6 dyads; 13.3%), and other reasons (15 dyads; 33.3%) (for details, see Northouse et al.[13]).

The average age of patients in the final sample (N = 235) was 63 years (standard deviation, 9.1 years; range, 42-90 years), and the average age of spouses was 59 years (standard deviation, 9.7 years; range, 34-84 years). Eighty-four percent of dyads were Caucasian, 14% were African American, and 2%
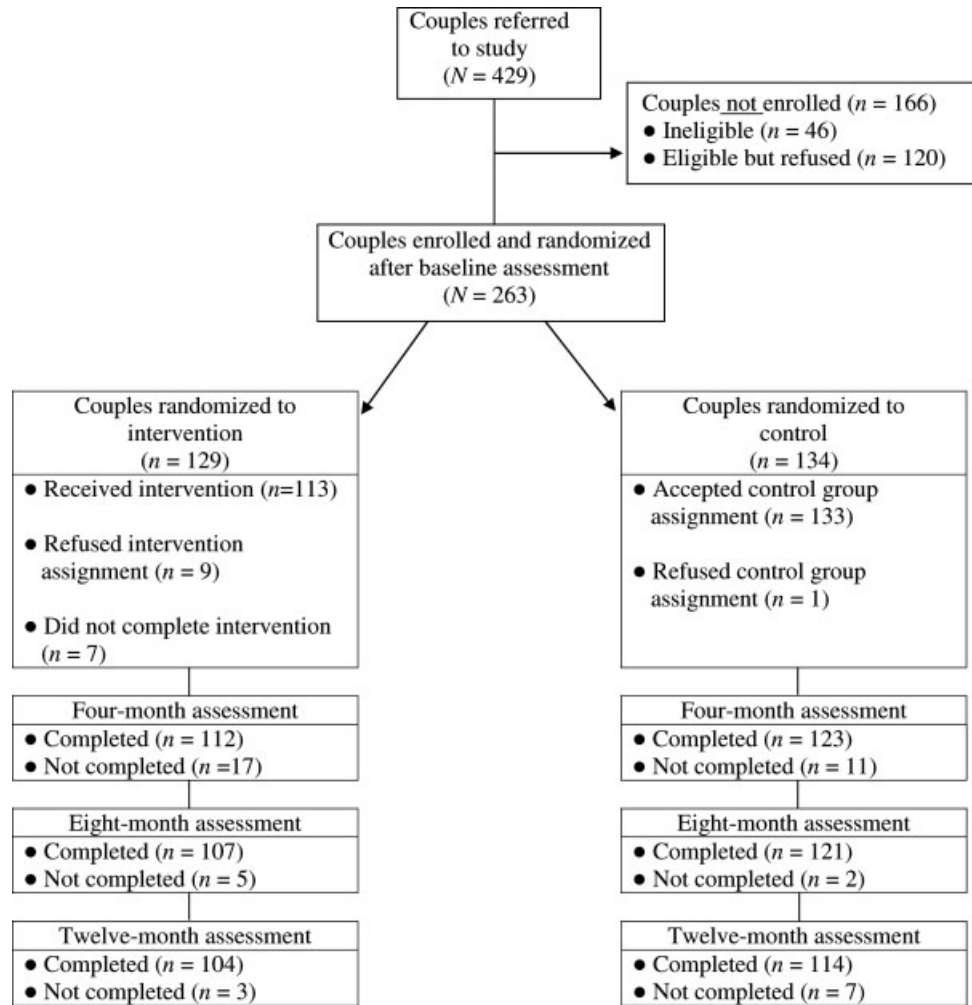
FIGURE 1. Flow of couples through clinical trial.

were Hispanic, Asian, Native American, or mixed race. Patients and spouses reported averages of 16 years and 15 years of formal education, respectively. The median family income ranged from $50,000 to $75,000.

Sixty-five percent of patients were in the newly diagnosed phase. Of those, 60% underwent prostatectomy, and 40% received external beam radiation. Fourteen percent of patients were in the biochemical recurrence phase, with 50% under observation and 50% under treatment (primarily hormones). Twenty-one percent of patients were in the advanced phase, with 36% receiving hormone treatments and 64% receiving hormone-refractory treatments (eg, chemotherapy). Thirty-seven percent of patients had a family history of cancer, and 68% had other health problems, such as arthritis or heart disease. Approximately 25% of the spouses had health problems, such as arthritis or back pain. There were no significant differences between

patients and spouses in the intervention and control groups on primary study variables or demographics at baseline, which demonstrated the effectiveness of randomization.

Major Study Outcomes

Table 1 provides adjusted means for patients in the intervention and control groups at the 4-, 8-, and 12-month assessments, controlling for their own baseline scores, using estimated values for missing data, and maintaining the sample size across all assessment periods. Table 2 provides comparable data for spouses.

Patient outcomes

There were no differences between intervention and control patients on any QOL variables. On the appraisal variables, the 2 groups did not differ on appraisal of illness, but they did differ on uncertainty.

Patients in the intervention group reported less uncertainty about their illness than controls at 4 months (mean score, 56.9 vs 60; $P < .05$).

Patient groups differed on 1 coping resource variable. Intervention patients reported more communication about the illness with their spouses than control patients at 4 months (mean score, 3.80 vs 3.69; $P < .05$). There were no differences between groups on general symptom distress or on prostate-specific symptoms. No significant effects of the intervention were observed for patients at 8 months or 12 months.

Spouse outcomes

Several intervention effects were observed for spouses (see Table 2). On the MOS SF-12, intervention spouses reported better *physical* QOL than controls at 8 months (mean score, 44.9 vs 42.9; $P < .05$) and at 12 months (mean score, 44.6 vs 42.3; $P < .01$), although there were no differences between groups at 4 months. In addition, intervention spouses had better SF-12 *mental* QOL scores (mean score, 50.9 vs 49; $P < .05$) and *overall* FACT-G QOL scores (mean score, 86.5 vs 83.5; $P < .01$) than controls at 4 months, but not at 8 months or 12 months.

There were several differences on the appraisal variables for spouses. Intervention spouses had significantly less negative appraisal of caregiving (mean score, 2.29 vs 2.44; $P < .01$), significantly less uncertainty about the illness (mean score, 59.5 vs 63.1; $P < .01$), and less hopelessness (mean score, 2.47 vs 3.07; $P < .05$) than control spouses at 4 months. Uncertainty continued to be lower for intervention spouses versus control spouses at 8 months (mean score, 59.5 vs 62.2; $P = .05$).

Among the coping resource variables, intervention spouses had higher self-efficacy about ways to manage the illness than control spouses at 4 months (mean score, 144.1 vs 138.8; $P < .05$) and 12 months (mean score, 143.8 vs 137.8; $P < .05$). In addition, intervention spouses had better communication with patients than control spouses across all 3 assessments: at 4 months (mean score, 3.74 vs 3.57; $P < .01$), 8 months (mean score, 3.66 vs 3.52; $P < .05$), and 12 months (mean score, 3.66 vs 3.50; $P < .01$). Although there were no differences in active coping at 4 months and 8 months, intervention spouses used more active coping at 12 months than control spouses (mean score, 30.5 vs 28.9; $P < .05$).

Finally, intervention spouses had significantly less general symptom distress of their own than control spouses (mean score, 5.10 vs 6.28; $P < .01$) and had fewer problems related to their husbands' urinary incontinence at 4 months (mean score, 1.60 vs 1.85; $P < .05$) and at 8 months (mean score, 1.53 vs 1.81; $P < .01$).

Moderator effects

We tested for 2 moderator effects: phase of illness (newly diagnosed, biochemical recurrence, advanced disease) and risk for distress. No moderation was observed, suggesting that the effectiveness of the intervention was not moderated by either variable.

DISCUSSION

One important finding of this study was the benefit spouses of men with prostate cancer received from a family-based intervention that was offered jointly to patients and spouses. The intervention had many positive effects, extending across a number of variables that improved spouses' appraisal of the caregiving experience, increased their ability to cope, and enhanced their physical and mental QOL. Although patients also obtained benefits from the intervention, the effects were far greater for their spouses.

Why did spouses benefit so much from the intervention? Spouses had a greater need for the intervention than patients. Prior research indicates that spouses have more distress than patients[1,3] yet receive less support.[4] The intervention provided spouses with information and support that reduced their negative appraisal of caregiving, decreased their uncertainty, and lessened their hopelessness. Spouses also learned ways to cope with the stress of caregiving and to manage the symptoms experienced by patients. These strategies may have accounted for spouses' higher caregiver efficacy, fewer problems with patients' symptoms (urinary), and better overall QOL than control spouses. McMillan et al.[27] observed that caregivers who learned coping skills had better QOL than caregivers who received support only. Spouses' coping resources (ie, self-efficacy, communication, active coping strategies) were better for the intervention group than for the control group at the 12-months follow-up, suggesting that intervention effects on these variables endured over time.

Spouses who received the intervention reported less symptom distress of their own at 4 months and better physical QOL than control spouses at 8 months and 12 months. These are particularly important findings, because caregiving stress has been associated with poorer physical health and higher mortality among caregivers.[28] Intervention spouses, who were encouraged to seek care for their own health problems and to engage in healthy lifestyle behaviors (exercise, nutrition), appeared to show

improved health. The improvements in physical QOL did not appear until 8 months and 12 months post-intervention, suggesting that positive changes in physical health may take time to develop.

Couples who participated in the intervention were able to communicate more effectively about the illness than control couples. This is noteworthy in view of multiple studies that have identified communication problems in couples with prostate cancer.[2] The intervention was offered jointly to patients and spouses, allowing both individuals to obtain first-hand information, to have their questions answered, and to hear the concerns of their partner. Manne et al.[3] offered an intervention to spouses only and observed no effects on marital communication, concluding that interventions designed to affect the marital system (ie, communication) need to include both partners.

Patients who participated in the intervention had 2 positive outcomes at initial follow-up (less uncertainty, better communication), but they had no sustained effects and no effects on symptoms or on their QOL. More targeted or higher dose interventions may be needed to address prostate-specific symptoms. For example, Mishel et al.[9] assisted patients with prostate cancer in managing urinary incontinence by teaching them Kegel exercises and offering weekly telephone reinforcement for 8 weeks. With regard to QOL scores, because the majority of patients were in the newly diagnosed phase, with high FACT-G QOL scores similar to those in the normal population,[29] there was little room for improvement. Giesler et al.[7] also observed no intervention effects on QOL outcomes in patients with newly diagnosed prostate cancer. Furthermore, all patients (intervention and control) had spouses as their primary caregivers, who may have buffered the stress of illness and lessened intervention effects on patients.

We also observed no differential effect of the intervention according to patients' phase of illness or risk for distress at baseline, both of which warrant further study. With fewer patients in the recurrent and advanced phases versus patients in the newly diagnosed phase, the power to detect moderation may have been limited. Furthermore, although risk for distress can predict accurately patients' later risk status, we need to examine more closely how risk status affects patients' response to a psychosocial intervention.

There were some limitations to the current study that should be noted. Because only a few intervention studies have been conducted with couples facing prostate cancer, multiple comparisons were conducted to examine possible intervention effects, increasing the possibility of Type I error (ie, chance findings). Furthermore, the numbers of patients in the biochemical and advanced phases were small and may have limited our power to detect possible moderation among the phases of illness. Finally, all patients had partners in this study, which limits the ability to generalize the current findings to patients without spouses.

Given the positive effects of the intervention, what are the implications for clinical practice? At a minimum, the findings suggest that spouses of men with prostate cancer need to be included in programs of care. Too often, they are viewed as outside observers or only as providers of care. Instead, clinicians need to recognize that spouses are affected by the cancer and to treat them as corecipients of care. If patients are willing, then clinicians should include spouses in consultation sessions. They need to inquire about spouses' concerns and provide information to facilitate their caregiving role. By intervening jointly with patients and spouses, clinicians can help both individuals to gain information and obtain support, which may reduce their uncertainty and facilitate communication about the illness. Ideally, structured and systematic programs of care would help couples to cope with the effects of cancer. Further research is needed on cost-effective ways to deliver programs of care to patients and spouses in busy clinic settings.

REFERENCES

1. Kornblith AB, Herr HW, Ofman US, et al. Quality of life of patients with prostate cancer and their spouses. The value of a data base in clinical care. *Cancer*. 1994;73:2791–2802.
2. Boehmer U, Clark JA. Communication about prostate cancer between men and their wives. *J Fam Pract*. 2001;50:226–231.
3. Manne S, Babb J, Pinover W, et al. Psychoeducational group intervention for wives of men with prostate cancer. *Psychooncology*. 2004;13:37–46.
4. Northouse LL, Mood DW, Montie JE, et al. Living with prostate cancer: Patients' and spouses' psychosocial status and quality of life. *J Clin Oncol*. 2007;25:4171–4177.
5. Thornton AA, Perez MA, Meyerowitz BE. Patient and partner quality of life and psychosocial adjustment following radical prostatectomy. *J Clin Psychol Med Settings*. 2004;11:15–30.
6. Davison BJ, Degner LF. Empowerment of men newly diagnosed with prostate cancer. *Cancer Nurs*. 1997;20:187–196.
7. Giesler RB, Given BA, Given CW, et al. Improving the quality of life of patients with prostate carcinoma. *Cancer*. 2005;104:752–762.
8. Lepore SJ, Helgeson VS. Psychoeducational support group enhances quality of life after prostate cancer. *Cancer Res Ther Contr*. 1999;8:81–91.
9. Mishel MH, Belyea M, Germino BB, et al. Helping patients with localized prostate carcinoma manage uncertainty and treatment side effects: nurse-delivered psychoeducational intervention over the telephone. *Cancer*. 2002;94:1854–1866.

10. Weber BA, Roberts BL, Resnick M, et al. The effect of dyadic intervention on self-efficacy, social support, and depression for men with prostate cancer. *Psychooncology*. 2004;13:47–60.

11. Giarelli E, McCorkle R, Monturo C. Caring for a spouse after prostate surgery: the preparedness needs of wives. *J Fam Nurs*. 2003;9:453–485.

12. Lazarus RS, Folkman S. Stress, Appraisal, and Coping. New York, NY: Springer; 1984.

13. Northouse LL, Rossett T, Phillips L, et al. Research with families facing cancer: the challenge of accrual and retention. *Res Nurs Health*. 2006;29:199–211.

14. Northouse L, Kershaw T, Mood D, et al. Effects of a family intervention on the quality of life of women with recurrent breast cancer and their family caregivers. *Psychooncology*. 2005;14:478–491.

15. Northouse LL, Walker J, Schafenacker A, et al. A family-based program of care for women with recurrent breast cancer and their family members. *Oncol Nurs Forum*. 2002;29:1411–1419.

16. Ware J, Kosinski M, Keller SD. A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. *Med Care*. 1996;34:220–233.

17. Cella D, Tulsky D, Gray G, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *J Clin Oncol*. 1993;11:570–579.

18. Oberst MT. Appraisal of Illness and Caregiving Scales: Manuals for Use. Detroit, Mich: Wayne State University; 1991.

19. Mishel M, Epstein D. Uncertainty in Illness Scales Manual. Tucson, Ariz: University of Arizona; 1990.

20. Beck AT, Weissman A, Lester D, et al. The measurement of pessimism: the Hopelessness Scale. *J Consult Clin Psychol*. 1974;42:861–865.

21. Carver CS. You want to measure coping but your protocol's too long: consider the Brief COPE. *Int J Behav Med*. 1997;4:92–100.

22. Lewis FM. Family Home Visitation Study Final Report. Bethesda, Md: National Cancer Institute, National Institutes of Health; 1996.

23. Mood D, Bickes J. Strategies to enhance self-care in radiation therapy. *Oncol Nurs Forum*. 1989;16(suppl):143.

24. Wei JT, Dunn RL, Litwin MS, et al. Development and validation of the Expanded Prostate Cancer Index Composite (EPIC) for comprehensive assessment of health-related quality of life in men with prostate cancer. *Urology*. 2000;56:899–905.

25. Weisman AD. Coping With Cancer. New York, NY: McGraw-Hill; 1979.

26. Worden JW. Psychosocial screening of cancer patients. *J Psychosoc Oncol*. 1983;1:1–10.

27. McMillan SC, Small BJ, Weitzner M, et al. Impact of coping skills intervention with family caregivers of hospice patients with cancer. *Cancer*. 2006;106:214–222.

28. Schulz R, Beach SR. Caregiving as a risk factor for mortality: the Caregiver Health Effects Study. *JAMA*. 1999;282:2215–2229.

29. Brucker PS, Yost K, Cashy J, Webster K, et al. General population and cancer patient norms for the functional assessment of cancer therapy-general (FACT-G). *Eval Health Prof*. 2005;28:192–211.