

# Effectiveness of an Interdisciplinary Palliative Care Intervention for Family Caregivers in Lung Cancer

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**BACKGROUND:** Family caregivers (FCGs) experience significant deteriorations in quality of life while caring for patients with lung cancer. In this study, the authors tested the effectiveness of an interdisciplinary palliative care intervention for FCGs of patients diagnosed with stage I through IV nonsmall cell lung cancer. **METHODS:** FCGs who were identified by patients as their primary caregivers were enrolled in a prospective, quasi-experimental study in which the usual care group was accrued first followed by the intervention group. FCGs in the intervention group were presented at interdisciplinary care meetings, and they also received 4 educational sessions organized in the physical, psychological, social, and spiritual domains. The sessions included self-care plans to support the FCG's own needs. Caregiver burden, caregiving skills preparedness, psychological distress, and FCG quality of life were assessed at baseline and after 12 weeks using validated measures. **RESULTS:** In total, 366 FCGs were included in the primary analysis. FCGs who received the interdisciplinary palliative care intervention had significantly better scores for social well being (5.84 vs 6.86;  $P < .001$ ) and had lower psychological distress scores (4.61 vs 4.20;  $P = .010$ ) at 12 weeks compared with FCGs in the usual care group. FCGs in the intervention group also had significantly less caregiver burden compared with FCGs in the usual care group ( $P = .008$ ). **CONCLUSIONS:** An interdisciplinary approach to palliative care in lung cancer resulted in statistically significant improvements in FCG's social well being and psychological distress and in less caregiver burden. *Cancer* 2015;121:3737-45. © 2015 American Cancer Society.

**KEYWORDS:** family caregiver, lung cancer, palliative care, quality of life, symptoms.

## INTRODUCTION

A cancer diagnosis can profoundly impact the quality of life (QOL) for both patients and their family caregivers (FCGs). The cancer caregiving role is associated with physical and psychological burden, and this may be more pronounced with lung cancer.<sup>1</sup> Numerous studies have documented cancer's negative effect on FCGs, including increased psychological distress, family/social/spouse relationship disruptions, higher incidence of cardiac diseases, and substantial impact on the FCG's economic well being.<sup>2-6</sup>

Many FCGs of patients with lung cancer report physical and mental health that is worse than population norms.<sup>7,8</sup> In a qualitative study, Mosher and colleagues observed that the most common FCG challenge included a profound sense of uncertainty about the future and the patient's prognosis, managing the patient's emotional reactions to lung cancer, and accomplishing practical tasks, including coordinating the patient's medical care.<sup>9</sup> Distressed FCGs reported 1 or more negative economic or social changes since diagnosis, including reductions in social and leisure activity participation and reduced work hours.<sup>10</sup> Many FCGs reported quitting work, losing their main source of family income, losing most or all of their savings, and making substantial lifestyle changes because of caregiving.<sup>10,11</sup> Despite the high level of clinically meaningful psychological distress, the majority of FCGs did not access mental health or support services, although many expressed an interest in professional help for emotional and practical needs.<sup>12</sup> Our previous research suggests that, as the patient transitions through initial diagnosis and treatment, caregiver burden and psychological distress increased, while perceived caregiving skills preparedness and QOL decreased over time.<sup>13</sup> Increased FCG psychological distress was associated with 3 factors, including the ability to maintain QOL (self-care component), the perception of caregiving preparedness and caregiving demands (FCG role component), and the emotional reaction to caregiving (FCG stress component).<sup>14</sup>

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**DOI:** 10.1002/cncr.29567, **Received:** March 23, 2015; **Revised:** June 3, 2015; **Accepted:** June 17, 2015, **Published online** July 6, 2015 in Wiley Online Library (wileyonlinelibrary.com)

FCGs receive minimal attention within the current health care system, in which the focus is primarily on the needs of patients. Evidence-based care models are needed to support FCGs in their caregiving role. The purpose of the current National Cancer Institute-supported Program Project was to test the effectiveness of an interdisciplinary palliative care intervention in FCGs of patients diagnosed with stage I through IV nonsmall cell lung cancer. The Program Project supported the simultaneous testing of the palliative care intervention in both patients and FCGs. This report presents findings from the FCG project as well as a comparative analysis of key patient and FCG outcomes (psychological distress and QOL). We hypothesized that FCGs who received the interdisciplinary palliative care intervention would experience improved QOL, lower psychological distress, reduced caregiver burden, and improved caregiving skills preparedness. We also hypothesized that the effect of the intervention on psychological distress and QOL would be different for patients and FCGs.

## MATERIALS AND METHODS

### **Study and Intervention Design**

A 2-group, prospective, sequential, quasi-experimental design was used in which FCGs were enrolled into the usual care group first followed by intervention group enrollment. This study design was selected, as opposed to a randomized design, to minimize the risk of usual care group contamination, resulting in potential confounding effects on outcomes. FCG enrollment was stratified based on matching patient's disease stage (early vs late). Enrollment occurred between November 2009 and December 2010 for the usual care group and between July 2011 and August 2014 for the intervention group. Data collection concluded in September 2014. The study was conducted at 1 National Cancer Institute-designated comprehensive cancer center in Southern California, and all study procedures and protocols were approved by the institutional review board.

The study's conceptual framework combined adult teaching principles, the National Comprehensive Cancer Network *Guidelines for Distress Screening*,<sup>15</sup> the Institute of Medicine (IOM) *Report on Cancer Care for the Whole Patient*,<sup>16</sup> the National Consensus Project *Clinical Practice Guidelines for Quality Palliative Care*,<sup>17</sup> and the self-care concept. The adult teaching principles acknowledge the need for education to be responsive to the individual's goals and preferences. The National Comprehensive Cancer Network *Guidelines on Distress Screening*, the

IOM report, and the National Consensus Project guidelines provided standards of care and recognized that the needs of FCGs are an integral component of quality psychosocial and palliative care. The self-care concept and evidence suggest that FCGs often forget to manage their own comorbidities and have decreasing ability to cope with the stresses of caregiving.<sup>1</sup> Therefore, FCG self-care support is essential to improving well being.

The palliative care intervention consisted of 3 key components. Nurses completed a comprehensive baseline QOL assessment for both patients and FCGs. Assessment results were transferred to a personalized palliative care plan, with QOL issues categorized into the physical, psychological, social, and spiritual domains. Guided by the palliative care plan, patients and FCGs were presented at weekly interdisciplinary care meetings. Nurses, palliative medicine clinicians, thoracic surgeons, medical oncologists, a geriatric oncologist, a pulmonologist, a social worker, a chaplain, a dietitian, a physical therapist, and key members of the research team attended the team meetings. Recommendations were made on how to support both patients and FCGs based on the assessments. These recommendations included symptom management and supportive-care referrals for patients and supportive-care referrals (social work, chaplaincy) and available community resources for FCGs. Overall, 139 interdisciplinary care meetings were conducted between July 2011 and August 2014, with each case presentation lasting approximately 20 minutes.

FCGs also received 4 educational sessions with content categorized by the 4 QOL domains (Table 1). Content for FCGs also included a personalized self-care plan with strategies to support FCG QOL. FCGs received a manual that contained all teaching content organized in the 4 QOL domains. The FCG teaching sessions averaged 28 minutes. FCGs and patients in the usual care group had access to all supportive and palliative care services while on study.

### **Participants**

Patients with stage I through IV nonsmall cell lung cancer were invited by their treating physicians to participate in the study. Once enrolled, patients were asked to identify an FCG to participate in the study. For this study, an FCG refers to either a family member or a friend identified by the patient as the primary caregiver. Patients who did not have an FCG were allowed to enroll in the study. Written informed consent was obtained for both patients and FCGs. FCGs were eligible if they were age 21 years or

**TABLE 1.** Family Caregiver Education Session Content

|                                |
|--------------------------------|
| Physical well being            |
| Fatigue                        |
| Pain                           |
| Appetite                       |
| Dyspnea/cough                  |
| Sleep                          |
| Nausea/vomiting                |
| Constipation/diarrhea          |
| Skin, nail, hair changes       |
| Psychological well being       |
| Anxiety                        |
| Depression                     |
| Anger                          |
| Cognitive changes              |
| Social well being              |
| Communication                  |
| Health care planning           |
| Relationships                  |
| Social support                 |
| Financial burden               |
| Sexuality                      |
| Spiritual well being           |
| Purpose/meaning                |
| Hope                           |
| Inner strength                 |
| Redefining self and priorities |
| Uncertainty                    |

older and had a matching patient enrolled in either the early stage or late-stage project.

### **FCG and Patient Outcome Measures**

FCG QOL was assessed using the FCG version of the City of Hope QOL Tool (COH-QOL-FCG). This 37-item instrument measures FCG QOL in the physical, psychological, social, and spiritual well being domains. Items are rated on a scale from 1 to 10, with higher scores representing worse QOL. A 10% to 20% difference in scores for the tool is considered clinically meaningful. The test-retest reliability was .89, and internal consistency was .69.<sup>18</sup> Caregiver burden was assessed using the Montgomery Caregiver Burden Scale. This 14-item tool measures the impact of caregiving on 3 dimensions of burden: objective, subjective demand, and subjective stress. Each item is scaled from 1 to 5, and higher scores represent higher burden. Internal consistency for the 3 dimensions ranges from .81 to .90.<sup>19,20</sup> Caregiving skills preparedness was assessed using the Archbold Caregiving Preparedness Scale. This 8-item scale, which is scored from 0 to 4, evaluates the FCG's comfort with the patient's physical and emotional needs. Higher scores represent better preparedness. Internal consistency on this scale ranges from .88 to .93.<sup>21</sup>

Patients' QOL and symptoms were assessed using the Functional Assessment of Cancer Therapy-Lung tool,

which contains 27 items that measures physical, social/family, emotional, and functional well being. The additional lung cancer subscale assesses disease-specific symptoms. All items are scored on a 5-point Likert scale from 0 (not at all) to 4 (very much). Higher scores indicate better QOL, and the total score ranges from 0 to 140.<sup>22</sup> Spiritual well being was assessed using the Functional Assessment of Chronic Illness Therapy-Spirituality Subscale. This is a 12-item, 5-point Likert scale that assesses sense of meaning, peace, and faith in illness. The total score ranges from 0 to 48, and higher scores indicate better spiritual well being.<sup>23</sup> The Distress Thermometer was used to assess patient and FCG psychological distress. The Distress Thermometer is an efficient, low-burden screening tool that uses a scale from 0 to 10, which higher scores indicating more distress.<sup>24</sup>

### **Study Procedures**

Patients and FCGs completed baseline questionnaires at enrollment. For the usual care group, FCGs completed follow-up questionnaires at 7 and 12 weeks, whereas patients were reevaluated at 6 and 12 weeks. For the intervention group, FCGs received the intervention's teaching component 6 weeks after the completion of patient teaching. This *delayed* design was used to prevent treatment effect contamination between patients and FCGs. Data collection for the intervention group was identical to the usual care group procedures. All patient and FCG data were collected during in-person encounters at outpatient clinics or through mailed questionnaires.

### **Statistical Analysis**

Data processing included scanning demographic and outcome measures and importing tracking data from an Access database. Data were analyzed using the Statistical Package for the Social Sciences (IBM SPSS Statistics for Windows, version 21.0, released 2012; IBM Corp, Armonk, NY.). All results are based on an intention-to-treat analysis. Consented FCGs who completed their baseline measurement were included for analysis (N = 366). After an accuracy audit, data were matched by identification numbers, and missing data were imputed using the SPSS Missing Values Analysis procedure and the Estimation and Maximization method. Missing data for FCGs whose patients died while on study (N = 24) were not imputed, because they were discontinued from the study. Selected demographic data were compared by group (intervention vs usual care) and by disease stage (stages I-III vs stage IV) using contingency table analysis

**TABLE 2.** Family Caregiver Demographic Characteristics by Group and Disease Stage

| Variable                                  | No. (%)          |                    | P    | No. (%)       |               | P     |
|---|------------------|--------------------|------|---------------|---------------|-------|
|   | Usual Care Group | Intervention Group |      | Stages I-III  | Stage IV      |       |
| Sex                                       |                  |                    |      |               |               |       |
| Men                                       | 59 (36.2)        | 80 (39.4)          | .588 | 51 (32.5)     | 88 (42.1)     | .065  |
| Women                                     | 104 (63.8)       | 123 (60.6)         |      | 106 (67.5)    | 121 (57.9)    |       |
| Education completed                       |                  |                    |      |               |               |       |
| Elementary school                         | 2 (1.2)          | 1 (0.5)            | .071 | 1 (0.6)       | 2 (1)         | .252  |
| Secondary/high school                     | 61 (37.4)        | 55 (27.1)          |      | 57 (36.3)     | 59 (28.2)     |       |
| College                                   | 100 (61.3)       | 147 (72.4)         |      | 99 (63.1)     | 148 (70.8)    |       |
| Marital status                            |                  |                    |      |               |               |       |
| Single                                    | 16 (9.9)         | 31 (15.3)          | .308 | 18 (11.5)     | 29 (13.9)     | .756  |
| Separated, divorced, widowed              | 13 (8)           | 16 (7.9)           |      | 12 (7.6)      | 17 (8.2)      |       |
| Married, partnered                        | 133 (82.1)       | 156 (76.8)         |      | 127 (80.9)    | 162 (77.9)    |       |
| Live alone                                |                  |                    |      |               |               |       |
| Yes                                       | 6 (3.7)          | 15 (7.4)           | .175 | 10 (6.4)      | 11 (5.3)      | .657  |
| Employed                                  |                  |                    |      |               |               |       |
| >32 h/wk                                  | 56 (34.4)        | 48 (23.6)          | .027 | 45 (28.7)     | 59 (28.2)     | 1.000 |
| Ethnicity                                 |                  |                    |      |               |               |       |
| Hispanic/Latino                           | 11 (6.7)         | 24 (11.8)          | .015 | 15 (9.6)      | 20 (9.6)      | .585  |
| NOT Hispanic/Latino                       | 145 (89)         | 178 (87.7)         |      | 140 (89.2)    | 183 (87.6)    |       |
| Unknown/unreported                        | 7 (4.3)          | 1 (0.5)            |      | 2 (1.3)       | 6 (2.9)       |       |
| Race                                      |                  |                    |      |               |               |       |
| American Indian                           | 2 (1.2)          | 0 (0)              | .001 | 0 (0)         | 2 (1)         | .042  |
| Asian                                     | 25 (15.3)        | 16 (7.9)           |      | 13 (8.3)      | 28 (13.4)     |       |
| Black or African American                 | 7 (4.3)          | 5 (2.5)            |      | 6 (3.8)       | 6 (2.9)       |       |
| Native Hawaiian or other Pacific Islander | 1 (0.6)          | 10 (4.9)           |      | 2 (1.3)       | 9 (4.3)       |       |
| White (includes Latino)                   | 115 (70.6)       | 167 (82.3)         |      | 132 (84.1)    | 150 (71.8)    |       |
| Other                                     | 13 (8)           | 5 (2.5)            |      | 4 (2.5)       | 14 (6.7)      |       |
| Religion                                  |                  |                    |      |               |               |       |
| Protestant                                | 68 (42)          | 81 (40.1)          | .171 | 77 (49.4)     | 72 (34.6)     | .088  |
| Catholic                                  | 47 (29)          | 56 (27.7)          |      | 34 (21.8)     | 69 (33.2)     |       |
| Jewish                                    | 5 (3.1)          | 16 (7.9)           |      | 12 (7.7)      | 9 (4.3)       |       |
| Muslim                                    | 1 (0.6)          | 0 (0)              |      | 0 (0)         | 1 (0.5)       |       |
| Buddhist                                  | 7 (4.3)          | 1 (0.5)            |      | 1 (0.6)       | 7 (3.4)       |       |
| Mormon/LDS                                | 2 (1.2)          | 2 (1)              |      | 0 (0)         | 4 (1.9)       |       |
| Jehovah's Witness                         | 1 (0.6)          | 1 (0.5)            |      | 0 (0)         | 2 (1)         |       |
| Seventh Day Adventist                     | 1 (0.6)          | 1 (0.5)            |      | 1 (0.6)       | 1 (0.5)       |       |
| Other/none                                | 30 (18.5)        | 44 (21.8)          |      | 31 (19.9)     | 43 (20.7)     |       |
| Income                                    |                  |                    |      |               |               |       |
| ≤\$50K                                    | 39 (23.9)        | 39 (19.2)          | .543 | 33 (21)       | 45 (21.5)     | .639  |
| >\$50K                                    | 92 (56.4)        | 123 (60.6)         |      | 96 (61.1)     | 119 (56.9)    |       |
| Declined to state                         | 32 (19.6)        | 41 (20.2)          |      | 28 (17.8)     | 45 (21.5)     |       |
| Classification of smoking history         |                  |                    |      |               |               |       |
| Current smoker                            | 14 (8.6)         | 15 (7.4)           | .829 | 13 (8.3)      | 16 (7.7)      | .194  |
| Former smoker                             | 63 (38.7)        | 75 (36.9)          |      | 67 (42.7)     | 71 (34)       |       |
| Nonsmoker                                 | 86 (52.8)        | 113 (55.7)         |      | 77 (49)       | 132 (58.4)    |       |
| Surgery in past 3 mo                      | 13 (8)           | 18 (8.9)           | .851 | 8 (11.3)      | 5 (5.4)       | .244  |
| Pack-years of smoking:                    | 26.45 ± 28.11    | 21.78 ± 28.49      | .126 | 27.15 ± 25.72 | 26.24 ± 23.33 | .814  |
| Mean ± SD                                 |                  |                    |      |               |               |       |
| Age: Mean ± SD, y                         | 57.23 ± 13.16    | 57.54 ± 14.31      | .834 | 57.23 ± 13.16 | 57.54 ± 14.31 | .834  |
| Total no. of chronic illnesses:           | 1.36 ± 1.56      | 1.40 ± 1.60        | .773 | 1.36 ± 1.56   | 1.40 ± 1.60   | .773  |
| Mean ± SD                                 |                  |                    |      |               |               |       |

LDS indicates Latter Day Saints; SD, standard deviation.

and the chi-square statistic or the Student *t* test, depending on the measurement level.

The study hypotheses for the 4 main outcomes (QOL, psychological distress, caregiver burden, and caregiving skills preparedness) were tested using factorial analysis of covariance controlling for baseline scores with disease stage as a blocking variable and group as the fac-

tor. The 3 caregiver burden subscales also were collapsed into high-burden and low-burden scores as established in the literature<sup>19,20</sup> and were analyzed using contingency tables with the chi-square statistic. FCG data were then merged with patient data, resulting in a total of 354 matched pairs to test the comparative analysis of patient and FCG psychological distress and QOL. A factorial,

**TABLE 3.** Multivariate Analysis of Family Caregiver Psychological Distress and Quality of Life by Group and Disease Stage

| Outcome                             | Usual Care Group (N = 157) |      |               | Intervention Group (N = 197) |      |               | $P_{\text{Main}}^a$ |
|-------------------------------------|----------------------------|------|---------------|------------------------------|------|---------------|---------------------|
|                                     | Mean Score                 | SD   | Adjusted Mean | Mean Score                   | SD   | Adjusted Mean |                     |
| Psychological distress <sup>b</sup> |                            |      |               |                              |      |               |                     |
| Early, stages I-III                 | 4.87                       | 2.87 | 4.90          | 4.15                         | 2.26 | 4.00          | .010                |
| Late, stage IV                      | 4.40                       | 2.89 | 4.54          | 4.25                         | 2.43 | 4.23          |                     |
| Total                               | 4.61                       | 2.88 |               | 4.20                         | 2.36 |               |                     |
| Physical QOL <sup>c</sup>           |                            |      |               |                              |      |               |                     |
| Early, stages I-III                 | 7.07                       | 1.76 | 7.08          | 7.27                         | 1.88 | 7.07          | .886                |
| Late, stage IV                      | 7.06                       | 1.78 | 7.22          | 7.26                         | 1.62 | 7.27          |                     |
| Total                               | 7.06                       | 1.76 |               | 7.26                         | 1.73 |               |                     |
| Psychological QOL <sup>c</sup>      |                            |      |               |                              |      |               |                     |
| Early, stages I-III                 | 5.38                       | 1.69 | 5.43          | 5.79                         | 1.28 | 5.39          | .803                |
| Late, stage IV                      | 5.13                       | 1.57 | 5.35          | 5.34                         | 1.43 | 5.44          |                     |
| Total                               | 5.24                       | 1.62 |               | 5.53                         | 1.38 |               |                     |
| Social QOL <sup>c</sup>             |                            |      |               |                              |      |               |                     |
| Early, stages I-III                 | 5.84                       | 1.98 | 5.81          | 6.86                         | 1.48 | 6.50          | <.001               |
| Late, stage IV                      | 6.13                       | 1.80 | 6.21          | 6.20                         | 1.82 | 6.44          |                     |
| Total                               | 6.00                       | 1.89 |               | 6.48                         | 1.71 |               |                     |
| Spiritual QOL <sup>c</sup>          |                            |      |               |                              |      |               |                     |
| Early, stages I-III                 | 6.67                       | 1.79 | 6.56          | 6.55                         | 1.41 | 6.39          | .043                |
| Late, stage IV                      | 6.43                       | 1.81 | 6.53          | 6.14                         | 1.70 | 6.25          |                     |
| Total                               | 6.54                       | 1.80 |               | 6.32                         | 1.59 |               |                     |
| Total QOL <sup>c</sup>              |                            |      |               |                              |      |               |                     |
| Early, stages I-III                 | 5.97                       | 1.48 | 5.98          | 6.40                         | 1.13 | 6.08          | .484                |
| Late, stage IV                      | 5.90                       | 1.38 | 6.07          | 5.97                         | 1.34 | 6.09          |                     |
| Total                               | 5.93                       | 1.42 |               | 6.16                         | 1.27 |               |                     |

QOL indicates quality of life; SD, standard deviation.

<sup>a</sup>These are  $P$  values for the main effect of group.

<sup>b</sup>Possible scores range from 0 to 10, with higher scores indicating more distress.

<sup>c</sup>Possible scores range from 0 to 10, with higher scores indicating better QOL.

repeated-measures analysis of covariance was used for this test, controlling for baseline scores with group as a between-subjects factor and the two 12-week scores (FCG and patient) as a within-subjects factor.

## RESULTS

### Baseline FCG Characteristics

After accounting for attrition, in total, 157 FCGs in the usual care group and 197 FCGs in the intervention group who had baseline assessments were included in the primary outcome analysis ( $N = 354$ ). Overall, 354 matched pairs ( $N = 153$  pairs for FCGs in the usual care group;  $N = 191$  pairs for FCGs in the intervention group) were included in the analysis of patient and FCG outcomes.

We observed significant between-group differences in baseline FCG demographic characteristics for work hours and race/ethnicity (Table 2). No statistically significant differences were observed for any other demographic characteristics.

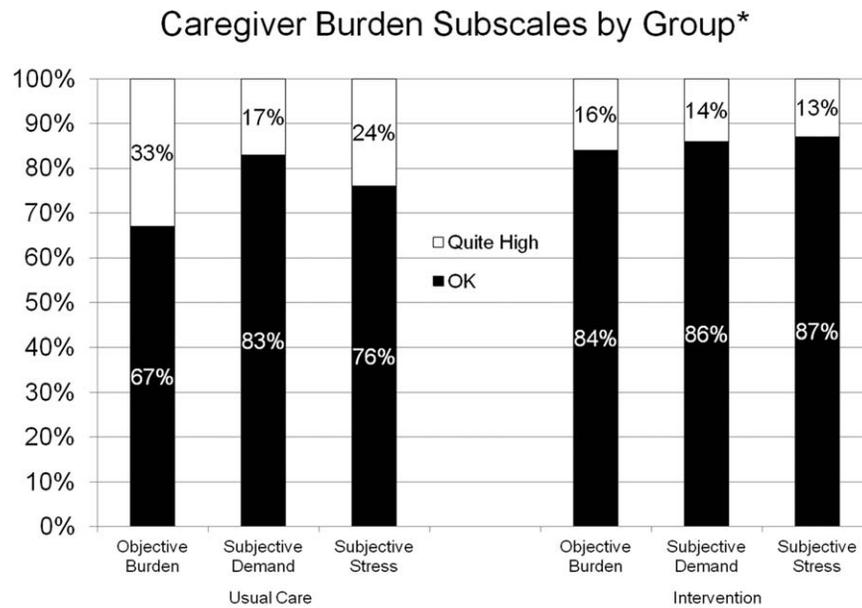
### QOL and Psychological Distress

Multivariate analysis of QOL and psychological distress revealed that FCGs in the intervention group had

significantly improved QOL in the social well being domain compared with FCGs in the usual care group, regardless of disease stage (Table 3). The intervention group had significantly lower psychological distress compared with the usual care group, regardless of disease stage. For spiritual well being, FCGs in the usual care group had significantly higher QOL compared with FCGs in the intervention group, regardless of disease stage.

### Caregiver Burden and Skills Preparedness

For caregiver burden subscale scores, we observed that, compared with FCGs in the usual care group, FCGs in the intervention group reported significantly fewer problems with objective burden or with perceived disruption of the tangible aspects of an FCG's life (33%;  $P < .001$ ). The intervention group had significantly fewer FCGs with elevated subjective stress (13%) compared with the usual care group (24%;  $P = .008$ ). There were no associations between groups for subjective demand, defined as the extent to which the FCG perceives care responsibilities to be overly demanding ( $P = .376$ ). We did not observe any statistically significant differences between groups or by disease stage for caregiver skills preparedness (Fig. 1, Table 4).



\*Percentage of FCGs in each of the subscales who answered "ok" or "quite high"

**Figure 1.** The impact of caregiving among family caregivers of patients diagnosed with stage I through IV nonsmall cell lung cancer was measured on 3 dimensions of burden (objective, subjective demand, and subjective stress) in the usual care group compared with the intervention group (family caregivers who received the interdisciplinary palliative care intervention).

**TABLE 4.** Family Caregiver Burden and Preparedness

| Outcome  | Usual Care Group (N = 157) |      |               | Intervention Group (N = 197) |      |               | <i>P</i> <sub>Main</sub> <sup>a</sup> |
|--|----------------------------|------|---------------|------------------------------|------|---------------|---------------------------------------|
|  | Mean Score                 | SD   | Adjusted Mean | Mean Score                   | SD   | Adjusted Mean |                                       |
| Caregiver preparedness (range, 1–5) <sup>b</sup> |                            |      |               |                              |      |               |                                       |
| Early, stages I-III                              | 3.69                       | 0.76 | 3.55          | 3.74                         | 0.67 | 3.70          |                                       |
| Late, stage IV                                   | 3.46                       | 0.74 | 3.47          | 3.40                         | 0.74 | 3.51          | .091                                  |
| Total  | 3.56                       | 0.76 |               | 3.55                         | 0.73 |               |                                       |
| Caregiver burden                                 |                            |      |               |                              |      |               |                                       |
| Objective burden (range, 6–30) <sup>b</sup>      |                            |      |               |                              |      |               |                                       |
| Early, stages I-III                              | 22.04                      | 4.66 | 22.22         | 20.93                        | 3.24 | 21.14         |                                       |
| Late, stage IV                                   | 21.50                      | 3.93 | 21.39         | 21.37                        | 2.92 | 21.18         | .069                                  |
| Total  | 21.74                      | 4.27 |               | 21.18                        | 3.07 |               |                                       |
| Subjective demand (range, 4–20) <sup>b</sup>     |                            |      |               |                              |      |               |                                       |
| Early, stages I-III                              | 11.62                      | 3.49 | 12.03         | 11.76                        | 2.97 | 11.56         |                                       |
| Late, stage IV                                   | 11.26                      | 3.40 | 11.35         | 12.03                        | 2.45 | 11.85         | .962                                  |
| Total  | 11.43                      | 3.44 |               | 11.91                        | 2.68 |               |                                       |
| Subjective stress (range, 4–20) <sup>b</sup>     |                            |      |               |                              |      |               |                                       |
| Early, stages I-III                              | 13.80                      | 3.26 | 14.02         | 13.00                        | 2.69 | 13.02         |                                       |
| Late, stage IV                                   | 13.60                      | 2.90 | 13.49         | 13.72                        | 2.48 | 13.66         | .116                                  |
| Total  | 13.69                      | 3.06 |               | 13.41                        | 2.59 |               |                                       |

SD indicates standard deviation.

<sup>a</sup>These are *P* values for the main effect of group.

<sup>b</sup>Note that higher scores indicate that the caregiver was more prepared.

<sup>c</sup>Note that higher scores indicate more burden.

**Patient and FCG Comparison**

Post-hoc analysis of patient and FCG outcomes for QOL and psychological distress (Table 5) revealed that patient’s physical and social QOL was significantly higher than

FCG’s QOL in the usual care group (*P* = .008 and *P* = .001, respectively). FCGs reported higher psychological QOL than patients, regardless of group assignment (*P* = .033 for usual care; *P* = .023 for intervention). Patients

**TABLE 5.** Differences Between Patient and Family Caregiver Distress and Quality of Life<sup>a</sup>

| Outcome                | Usual Care Group (N = 153) |       |               | Intervention Group (N = 191) |       |               | P                 |                          |
|------------------------|----------------------------|-------|---------------|------------------------------|-------|---------------|-------------------|--------------------------|
|                        | Mean Score                 | SD    | Adjusted Mean | Mean Score                   | SD    | Adjusted Mean | Main <sup>b</sup> | Interaction <sup>c</sup> |
| Psychological distress |                            |       |               |                              |       |               |                   |                          |
| FCG                    | 4.58                       | 2.98  | 4.69          | 4.20                         | 2.39  | 4.12          |                   |                          |
| Patient                | 3.09                       | 2.70  | 3.15          | 2.29                         | 2.19  | 2.25          | .154              | .317                     |
| Physical QOL           |                            |       |               |                              |       |               |                   |                          |
| FCG                    | -0.058                     | 1.01  | -0.016        | 0.050                        | 1.00  | 0.016         |                   |                          |
| Patient                | -0.327                     | 1.18  | -0.246        | 0.135                        | 0.83  | 0.070         | .286              | .015                     |
| Social QOL             |                            |       |               |                              |       |               |                   |                          |
| FCG                    | -0.146                     | 1.05  | -0.137        | 0.134                        | 0.95  | 0.129         |                   |                          |
| Patient                | 0.084                      | 0.765 | 0.132         | 0.148                        | 0.914 | 0.109         | .059              | .008                     |
| Psychological QOL      |                            |       |               |                              |       |               |                   |                          |
| FCG                    | -0.102                     | 1.09  | 0.006         | 0.089                        | 0.932 | 0.003         |                   |                          |
| Patient                | -0.183                     | 0.98  | -0.159        | 0.181                        | 0.98  | 0.161         | .968              | <.001                    |
| Spiritual QOL          |                            |       |               |                              |       |               |                   |                          |
| FCG                    | 0.081                      | 1.06  | 0.091         | -0.046                       | 0.94  | -0.054        |                   |                          |
| Patient                | -0.083                     | 0.03  | 0.002         | 0.156                        | 0.99  | 0.087         | .670              | .018                     |

FCG indicates family caregiver; QOL, quality of life; SD, standard deviation.

<sup>a</sup>QOL was transformed to Z-scores, because the FCG and patient QOL instruments were different yet contained the same 4 components.

<sup>b</sup>These are P values for the main effect of group.

<sup>c</sup>These are P values for the interaction between group and disease stage.

had significantly higher spiritual QOL than FCGs in the intervention group ( $P = .028$ ). There were no statistically significant main effects or interaction effects for psychological distress.

## DISCUSSION

Palliative care, as recommended by the IOM, consensus groups, and professional organizations, including the American Society of Clinical Oncology, is an integral component of quality cancer care. Over the last decade, several randomized controlled trials have tested the effects of early palliative care for cancer patients, including patients with nonsmall cell lung cancer. However, few high-profile trials have tested the concurrent effects of early palliative care on FCGs, and most interventions were designed only for patients with metastatic disease. To our knowledge, this is 1 of the first large, comparative trials targeting FCGs of patients with all disease stages in which patients and their FCGs simultaneously participated in the intervention. This approach is recommended by the National Consensus Project for Quality Palliative Care<sup>25</sup> and acknowledges that both the patient and the family unit are affected by a cancer diagnosis. This study also adds to the growing evidence that palliative care integrated with disease-focused care benefits patients and FCGs across disease stages.

The intervention provided a replicable model for elements that should be included in FCG palliative care interventions, including comprehensive FCG QOL assessment, interdisciplinary care recommendations made

concurrently for patients and FCGs as a unit, and support of FCG's QOL needs through education sessions. The tailored approach to educational needs allowed for content delivery endorsed by each specific FCG as a high priority. Finally, although self-care is considered an essential content area for interventions, a recent meta-analysis indicated that many published FCG interventions only included self-care as a secondary focus or as an afterthought.<sup>26</sup> Our focus on FCGs' self-care needs as a key intervention component recognizes the importance of self-care in supporting FCG QOL.

Study results revealed that an interdisciplinary approach to palliative care for FCGs resulted in significant improvements in social QOL, psychological distress, and caregiver burden. Other studies have reported similar findings.<sup>27,28</sup> We did not observe significant differences by group in FCGs' physical or psychological QOL and caregiving preparedness. Studies have demonstrated that increases in perceived preparedness may not be observed in the short term but over longer periods.<sup>29,30</sup> The short study follow-up (12 weeks) may have resulted in the lack of statistical significance for preparedness, although the scores improved. Results for spiritual QOL revealed that FCGs in the usual care group reported significantly improved scores compared with FCGs in the intervention group. In our comparative analysis of patients and FCGs, we also observed different intervention effects on psychological distress and QOL. Although this analysis cannot definitively determine why the intervention did not have a significant impact on spiritual QOL and had differential

impact for patients and FCGs, a possible explanation may be an insufficiency in the intervention *dose* and content on supporting FCGs' spiritual QOL and other domains. The patient and FCG outcome variations may be explained by differences in trajectory of distress and QOL. Identification of the appropriate dosing of FCG interventions has been challenging, and future studies should aim to determine an ideal dosing for FCG interventions and gain a better understanding of the impact of concurrent palliative care on patient and FCG outcomes.<sup>26,31</sup>

Several study limitations warrant further discussion. The nonrandomized design can result in temporal bias related to care pattern changes over time and potentially may serve as a source of bias for intervention effect. However, the study was conducted over a relatively short period (2009-2014), so the effects should be minimal. Second, the study design did not allow for identifying specific intervention components that resulted in the observed FCG outcomes. This potentially could involve a tremendous amount of resources, a larger sample size, and a study design that includes multiple treatment arms to deconstruct intervention components and treatment effects. The inclusion of patients who had disease stages I through III as *early*, regardless of treatments received, may have contributed to the lack of differences when comparing FCGs by patient's disease stage. Finally, this was a single-site trial, and the findings may not be generalizable to other disease populations or settings.

In conclusion, the current results support recommendations from the IOM and others for quality cancer care through early, concurrent palliative care that includes FCGs from the point of diagnosis to the end of life. Future studies are needed to test the long-term effects of interventions on FCG QOL and resource use, to replicate the intervention in FCGs for other cancer diagnoses, and to assess its generalizability in community settings.

## FUNDING SUPPORT

The research described was supported by grant P01 CA136396 (Betty Ferrell, PhD, FAAN, principal investigator) from the National Cancer Institute. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the National Cancer Institute or the National Institutes of Health.

## CONFLICT OF INTEREST DISCLOSURES

The authors made no disclosures.

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