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**Prevalence, Severity, and Impact of Symptoms in Family Caregivers of Patients Undergoing
Radiation Therapy for Prostate Cancer**

by

Barbara A. Swore Fletcher

THESIS

Submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

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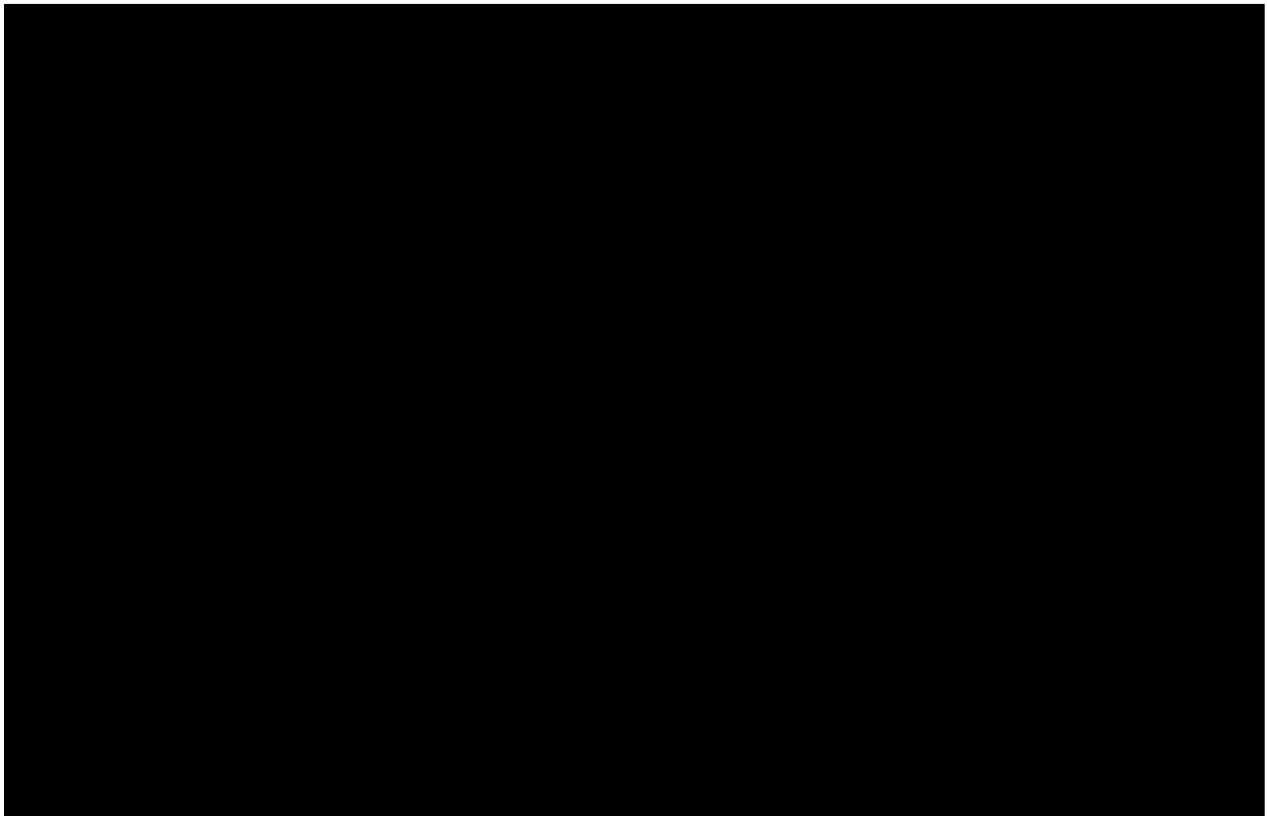
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Prevalence, Severity, and Impact of Symptoms in Family Caregivers of Patients
Undergoing Radiation Therapy for Prostate Cancer

Barbara A. Swore Fletcher

ABSTRACT

PURPOSE - In a sample of family caregivers (FCs) of patients with prostate cancer who were to begin radiation therapy (RT), the purposes were to: determine the prevalence and severity of depression, anxiety, pain, sleep disturbance, and fatigue; determine the relationships among these symptoms and between these symptoms and FC outcomes of functional status and quality of life (QOL); and evaluate for differences in functional status and QOL between FCs with low and high levels of these symptoms.

METHODS - FCs were recruited before the patient initiated RT and completed Center for Epidemiological Studies-Depression Scale, Spielberger State Trait Anxiety Inventory, Lee Fatigue Scale, General Sleep Disturbance Scale, and a numeric rating scale for worst pain intensity.

RESULTS - Sixty female FCs participated in the study (mean age = 64.2 years; average Karnofsky Performance Status score = 94.0). Based on established cutpoints for each instrument, 12.2% of the FCs had clinically significant levels of depression, 40.7% anxiety, 15.0% pain, 36.7% sleep disturbance, and 33.3% morning fatigue and 30.0% evening fatigue. Over 30% of FCs had clinically significant levels of anxiety, sleep disturbance, and fatigue. FCs with clinically significant levels of trait anxiety, pain, sleep disturbance, and morning fatigue had significantly lower functional status scores. FCs with clinically significant levels of depression, anxiety, pain, and fatigue had significantly lower QOL scores.

CONCLUSIONS - A high percentage of FCs experience clinically significant levels of a variety of symptoms. These symptoms have a negative effect on the FC's functional status and QOL.

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Figure 2 - For each symptom, differences in the physical (A), psychological (B), social (C), and spiritual (D) subscale scores of the Quality of Life Scale – Family Version between family caregivers in the low and high symptom groups are shown. Values are expressed as means and standard deviations. The * represents significant differences between the groups at a p-value of ≤ 0.05 .

Introduction

An estimated 44.4 million Americans provide some level of care to an adult family member and this number is likely to increase.¹ While several studies have found higher levels of depressive symptoms and mental health problems in family caregivers (FCs) of patients with dementia,^{2,3} little is known about the prevalence and severity of symptoms of FCs of patients with cancer.

In a comprehensive review of the symptom experience in FCs of patients with cancer (Fletcher, Dodd, Schumacher, and Miaskowski, in review), only 25 descriptive studies were identified. The most frequently assessed symptom was depression (92% of the studies), followed by anxiety (32%), fatigue (24%), and sleep disturbance (20%). No studies were found that evaluated pain in FCs of patients with cancer. Of note, higher symptom severity scores in FCs were associated with decreases in quality of life (QOL),⁴⁻⁸ health status,^{6,8-11} and life satisfaction.¹² However, because of the paucity of research, no definitive conclusions can be drawn about the prevalence, severity, and impact of each of these symptoms in FCs of patients with cancer.

Therefore, the purposes of this study, in a sample of FCs of patients with prostate cancer who were to begin radiation therapy (RT) were to: determine the prevalence and severity of depression, anxiety, pain, sleep disturbance, and fatigue; determine the relationships among these symptoms and between these symptoms and FC outcomes of functional status and QOL; and evaluate for differences in functional status and QOL between those FCs with low and high levels of depression, anxiety, pain, sleep disturbance, and fatigue.

Methods

Participants and Settings - This descriptive, correlational study is part of a longitudinal study that evaluated multiple symptoms in patients who underwent primary or adjuvant RT and their FCs. The patients and their FCs were recruited from two RT departments at the time of the patient's simulation visit. Patients had been diagnosed with prostate cancer for 9.7 ± 15.1 months (range 1.9 to 93.3 months). The study was approved by the Committee on Human Research at each of the study sites.

Following recruitment of the patients with prostate cancer, they were asked to identify the person most involved in their care (i.e., their FC). If the FC was with the patient, the research nurse explained the study and obtained written informed consent from the FC. FCs who were not with the patient were contacted by phone to determine their interest in study participation. The research nurse visited those FCs at home, obtained informed consent, and had them complete the baseline questionnaires.

FCs were eligible to participate if they: were an adult (≥ 18 years of age); were able to read, write, and understand English; gave written informed consent; had a Karnofsky Performance Status (KPS) score of > 60 ; were living with the patient; and did not have a diagnosed sleep disorder.

Instruments - The study instruments included a demographic questionnaire, the KPS scale,¹³ the Center for Epidemiological Studies-Depression Scale (CES-D),¹⁴ the Spielberg State Trait Anxiety Inventory (STAI-T and STAI-S),¹⁵ a descriptive numeric rating scale (NRS) for worst pain intensity,¹⁶ the General Sleep Disturbance Scale

(GSDS),¹⁷ the Lee Fatigue Scale (LFS),¹⁸ and the Quality of Life Scale-Family Version (QOL-FV).¹⁹

The demographic questionnaire provided information on age, gender, marital status, education, ethnicity, employment status, and the presence of a number of comorbid conditions. In addition, FCs completed the KPS scale.¹³

The CES-D consists of 20 items selected to represent the major symptoms in the clinical syndrome of depression. Scores can range from 0 to 60, with scores ≥ 16 indicating the need for participants to seek a clinical evaluation for major depression. The CES-D has well-established concurrent and construct validity.^{20,21} In the current study, the Cronbach's alpha for the CES-D was 0.84.

The STAI-T and STAI-S each consist of 20 items that are rated from 1 to 4. The scores for each scale are summed and can range from 20 to 80. A higher score indicates greater anxiety. The STAI-T measures an individual's predisposition to anxiety determined by his/her personality make up. The STAI-S measures an individual's transitory emotional response to a stressful situation. The STAI-T and STAI-S have well-established criterion and construct validity and internal consistency reliability coefficients.²²⁻²⁴ For this study, the Cronbach's alphas for the STAI-T and the STAI-S were 0.89 and 0.93, respectively.

Worst pain intensity was evaluated using a descriptive NRS that ranged from 0 (no pain) to 10 (excruciating pain). A descriptive NRS is a valid and reliable measure of pain intensity.¹⁶

The GSDS consists of 21 items that evaluate various aspects of sleep disturbance. Each item was rated on a NRS that ranged from 0 (never) to 7 (every day), and the 21 items were summed to yield a total score that could range from 0 (no disturbance) to 147 (extreme disturbance). The GSDS has well-established validity and reliability in shift workers, pregnant women, and patients with cancer and HIV.^{17,25-29} In the current study, the Cronbach's alpha for the GSDS total score was 0.79.

A fatigue severity score was calculated as the mean of the 13 items from the LFS and could range from 0 to 10, with higher scores indicating higher levels of fatigue severity. The LFS has been used to measure the severity of fatigue in healthy individuals,^{18,28} as well as in patients with cancer,³⁰ and HIV.²⁷ The LFS was chosen as the fatigue measure for this study because it is relatively short and easy to administer. In addition, it does not focus on cancer fatigue, and as such, is appropriate for FCs. The LFS has established validity and internal consistency reliability coefficients.¹⁸ In this sample, the Cronbach's alphas for the fatigue scale were 0.96 (morning) and 0.95 (evening).

The QOL-FV consists of 37 items that measure four dimensions of QOL in FCs of patients with cancer using 0 to 10 NRSs.³¹ A total QOL score as well as subscale scores were calculated, with higher scores indicating a better QOL. In the present study, the Cronbach's alpha for the total QOL score was 0.95.

After obtaining written informed consent, FCs completed all of the study questionnaires. The LFS was completed in the evening prior to bed (i.e., evening fatigue) and again upon awakening (i.e., morning fatigue) for two consecutive days. This

assessment coincided with the patients' simulation visit and was considered the baseline assessment for the larger longitudinal study.

Statistics - Data were analyzed using SPSS version 14. Descriptive statistics and frequency distributions were generated for the sample characteristics and symptom severity scores. Pearson Product Moment correlation coefficients were calculated to determine the relationships between each of the symptom severity scores and KPS and QOL scores. In order to determine the prevalence rates for the various symptoms, cutpoints were chosen for each of the symptom inventories based on published reports of clinically meaningful differences. The cutpoints for each of the instruments were: CES-D ≥ 16 ,¹⁴ STAI-T ≥ 31.8 , STAI-S ≥ 32.2 ,¹⁵ worst pain ≥ 7.0 ,³² GSDS ≥ 43.0 ,¹⁷ morning fatigue LFS ≥ 3.2 ,¹⁸ and evening fatigue LFS ≥ 5.6 .¹⁸ In addition, independent Student's t-tests were used to evaluate for differences in functional status (KPS score) and QOL (total QOL-FV and subscale scores) between those FCs with low and high levels of each symptom. A p-value of less than 0.05 was considered statistically significant.

Results

Family Caregiver Characteristics - As summarized in Table 1, the majority of the FCs were older (64.2 ± 8.8 years), Caucasian (80.0%), married/partnered (93.3%), and well educated (15.2 ± 2.8 years). Twenty-three different comorbid conditions were identified by at least one FC. The mean number of comorbid conditions was 4.8 ± 3.0 .

Prevalence and Severity of Symptoms in FCs - The mean symptom severity scores for the total sample, as well as the percentage of FCs in the low and high symptom groups and their mean symptom severity scores, are listed in Table 2.

Depression – The mean CES-D score for the total sample was 8.4 ± 6.5 . Twelve percent of FCs had CES-D scores of ≥ 16 . The mean CES-D score for the high symptom group was 21.0 ± 5.2 .

Anxiety – The mean trait and state anxiety scores for the total sample were 35.3 ± 9.9 and 32.6 ± 10.6 , respectively. Both of these scores are above the cutpoint for clinically significant levels of anxiety. Approximately 57.8% of the FCs were categorized in the high group based on their mean trait anxiety scores and 40.7% were categorized in the high group based on their mean state anxiety scores.

Pain – The mean worst pain intensity score for the total sample was 1.3 ± 3.1 . Only 15% of the FCs reported a worst pain score of ≥ 7 (mean score was 8.2 ± 1.0).

Sleep Disturbance – The mean GSDS score for the total sample was 39.9 ± 16.2 . Over 36% of the FCs reported GSDS scores that were above the cutpoint of 43.0.

Fatigue – In the total sample, scores for morning fatigue (2.5 ± 2.1) were lower than those reported for evening fatigue (4.3 ± 2.3). Approximately 30% of the FCs reported morning and evening fatigue scores that were above the cutpoints for clinically significant levels of fatigue.

Relationships among the various symptoms - Table 3 lists the correlations among the various symptoms. Significant moderate to strong positive correlations were found among the majority of symptoms. Of note, ratings of evening fatigue were not correlated with the majority of the other symptoms.

Relationships among symptoms and functional status and QOL - As shown in Table 4, significant negative correlations were found between KPS scores and the symptoms of

depression, trait anxiety, worst pain, sleep disturbance, and morning fatigue. A similar trend was found with all of the subscale scores as well as the total QOL score. As the severity of most of the symptoms increased, the majority of the QOL subscale scores decreased.

Differences in functional status and QOL scores between FCs in the low and high symptom groups

KPS Score - The mean KPS score for the entire sample of FCs was high (mean 94.0 ± 10.5). As shown in Figure 1A, significantly lower KPS scores were reported by FCs in the high symptom group compared to the low group for trait anxiety ($t = 2.3, p = 0.025$), worst pain ($t = 2.8, p = 0.007$), sleep disturbance ($t = 2.1, p = 0.047$), and morning fatigue ($t = 2.2, p = 0.037$).

QOL-FV Total and Subscale Scores - The mean total QOL-FV score for the entire sample was 7.2 ± 1.4 . As shown in Figure 1B, significantly lower total QOL scores were reported by FCs in the high symptom group compared to the low symptom group for depression ($t = 3.7, p = 0.001$), trait anxiety ($t = 4.8, p < 0.0001$), state anxiety ($t = 4.5, p < 0.0001$), worst pain ($t = 2.1, p = 0.04$), morning fatigue ($t = 5.2, p < 0.0001$), and evening fatigue ($t = 2.5, p = 0.014$).

QOL-FV Physical Subscale - The mean QOL-FV physical subscale score for the entire sample was 8.1 ± 1.7 . As shown in Figure 2A, significantly lower physical subscale scores were reported by FCs in the high symptom group compared to the low symptom group for depression ($t = 2.0, p = 0.05$), trait anxiety ($t = 3.8, p < 0.0001$), state

anxiety ($t = 3.6, p = 0.001$), worst pain ($t = 2.3, p = 0.05$), sleep disturbance ($t = 3.0, p = 0.006$), morning fatigue ($t = 3.7, p = 0.001$), and evening fatigue ($t = 4.1, p < 0.0001$).

QOL-FV Psychological Subscale – The mean QOL–FV psychological subscale score for the entire sample was 6.5 ± 1.7 . As shown in Figure 2B, significantly lower psychological subscale scores were reported by FCs in the high symptom group compared to the low symptom group for depression ($t = 3.1, p = 0.003$), trait anxiety ($t = 5.7, p < 0.0001$), state anxiety ($t = 4.6, p < 0.0001$), morning fatigue ($t = 5.6, p < 0.0001$), and evening fatigue ($t = 2.0, p = 0.05$).

QOL-FV Social Subscale – The mean QOL–FV social subscale score for the entire sample was 7.6 ± 1.7 . As shown in Figure 2C, significantly lower social subscale scores were reported by FCs in the high symptom group compared to the low symptom group for depression ($t = 3.1, p = 0.003$), trait anxiety ($t = 3.3, p = 0.002$), state anxiety ($t = 3.2, p = 0.002$), morning fatigue ($t = 4.2, p = 0.0001$), and evening fatigue ($t = 2.9, p = 0.005$).

QOL-FV Spiritual Subscale – The mean QOL–FV spiritual subscale score for the entire sample was 7.4 ± 1.4 . As shown in Figure 2D, a significantly lower spiritual subscale score was reported by FCs in the high symptom group compared to the low symptom group only for state anxiety ($t = 2.2, p = 0.031$).

Discussion

This study is the first to evaluate the prevalence and severity of five common symptoms in the same sample of FCs of patients with prostate cancer. Of note, for state and trait anxiety and morning fatigue, the mean symptom severity scores for the total

sample were above the established cutoffs for clinically significant symptom severity. In addition, for trait and state anxiety, as well as for sleep disturbance and morning and evening fatigue, 30% to 58% of the sample was found to have clinically significant symptom severity scores. As noted in Table 2, all of the prevalence rates for these five symptoms in the high group are higher than the lowest prevalence rates reported for depression,³³⁻³⁶ anxiety,³³ chronic pain,³⁷⁻⁴¹ sleep disturbance,⁴²⁻⁴⁵ and fatigue,⁴⁶ in the general population.

In addition to the high prevalence rates for these symptoms, findings from this study suggest that these symptoms have negative effects on FC's functional status and QOL. Higher levels of depression, trait anxiety, worst pain, sleep disturbance, and morning fatigue were associated with lower KPS scores even in this relatively small sample of women who reported high levels of function. Even stronger negative correlations were found among all of the symptom severity scores except worst pain, and the total and subscale scores of the QOL-FV. Taken together, these findings confirm those of two previous studies of the negative impact of symptoms on the functional status of FCs.^{5,6}

One of the advantages of the symptom scales used in this study is that they have established cutpoints for clinically significant scores. Therefore, we were able to evaluate the impact of clinically significant levels of each of these symptoms on FC outcomes. FCs with high levels of trait anxiety, worst pain, sleep disturbance, and morning fatigue reported significantly lower KPS scores. It is important to note that the differences in KPS scores between the high and low groups for each symptom represent not only

statistically but clinically significant differences in functional status based on calculations of effect sizes (i.e., $d = 0.59$ for trait anxiety, $d = 1.06$ for worst pain, $d = 0.68$ for sleep disturbance, $d = 0.80$ for morning fatigue, where $d = \text{mean of the low group} - \text{mean of the high group} / \text{standard deviation of the total sample}$ or the difference between the two means in standard deviation units). Similarly, the differences in the total QOL scores between the high and low groups based on a calculation of effect size were clinically meaningful for depression ($d = 1.3$), trait anxiety ($d = 1.1$), state anxiety ($d = 1.1$), worst pain ($d = 0.7$), morning fatigue ($d = 1.1$), and evening fatigue ($d = 0.7$). This conclusion is based on reports that suggest that minimally important differences in QOL are in the range of 0.20 to 0.50 standard deviation units.⁴⁷⁻⁴⁹

A surprising finding in this study is the relatively low prevalence of pain (only 15%) in this sample of older women. This finding may be attributed to the fact that the cutoff for pain was relatively high (worst pain score of 7). However, this cutpoint was chosen because in a previous study it was associated with deleterious effects on function.³² However, in the group of FCs who reported pain, 82% had pain at or above this cutpoint. In addition, the most common comorbidities reported by this group of FCs were back problems (100%), headaches (64%), and arthritis (55%).

Several limitations of this study are worth noting. The generalizability of the study findings is limited by inclusion of only female FCs and because the majority of these FCs were Caucasian and well-educated. In addition, these FCs were caring for patients who had early stage prostate cancer who were relatively well. Therefore, these

findings may be an underestimate of the symptom experience of FCs of patients with cancer.

Despite these limitations, the findings from this relatively small sample of female FCs suggest that clinically significant levels of anxiety, sleep disturbance, and fatigue occur in over 30% of FCs. In addition, these symptoms as well as depression and pain have negative effects on FC outcomes. Additional research is warranted to determine the co-occurrence of multiple symptoms and symptom clusters in FCs, as well as how these symptoms change over time and in relationship to the patient's disease trajectory. In the meantime, oncology clinicians need to be aware of the symptom burden of the FCs of their patients and the potential impact that these symptoms may have on the FC's ability to provide care to the patient.

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Table 1

Demographic characteristics and comorbid conditions of the family caregivers (n = 60) of men with prostate cancer

Characteristics	Mean (SD)
Age (years)	64.2 (8.8)
Education (years)	15.2 (2.8)
Karnofsky Performance Status Score	94.0 (10.5)
Gender	%
Female	100.0
Ethnicity	
African American	11.7
Asian or Pacific Islander	3.3
Caucasian	80.0
Other	5.0
Marital Status	
Married/partnered	93.3
Other	6.7
Employment Status	
Work for pay	36.7
Other	63.3
Lives with patient	
Yes	98.3
No	1.7
Comorbid Conditions	
Back problems	49.2
Arthritis	43.1
Hypertension	36.2
Headaches	35.6
Hemorrhoids	28.8

SD = standard deviation

Table 2

Prevalence of and differences in the mean symptom severity scores between the low and high symptom groups

Symptom Inventory and Cutpoint	Total Sample Symptom Severity Score		Low Group (below cutpoint)		High Group (above cutpoint)		Prevalence of symptoms in general population
	Mean (SD)	% (n)	Mean (SD)	% (n)	Mean (SD)	%	
Depression (CES-D) High \geq 16	8.4 (6.5)	87.9 (51)	6.7 (4.4)	12.1 (7)	21.0 (5.2)	12.1 (7)	2.6-9.6
Trait Anxiety (STAI-T) High \geq 31.8	35.3 (9.6)	42.4 (25)	26.3 (3.1)	57.6 (34)	42.0 (6.9)	57.6 (34)	16.9-19.5
State Anxiety (STAI-S) High \geq 32.2	32.6 (10.6)	59.3 (35)	26.0 (3.8)	40.7 (24)	42.2 (9.9)	40.7 (24)	10.8-24.4 chronic pain
Worst pain High \geq 7.0	1.4 (3.1)	85.0 (51)	0.2 (1.0)	15.0 (9)	8.2 (1.0)	15.0 (9)	27.7-37.2 insomnia
Sleep Disturbance (GSDS) High \geq 43.0	39.9 (16.2)	63.3 (38)	30.0 (7.9)	36.7 (22)	56.8 (12.1)	36.7 (22)	22.0-38.0
Morning Fatigue (LFS) High \geq 3.2	2.5 (2.1)	66.7 (40)	1.2 (1.0)	33.3 (20)	5.0 (1.2)	33.3 (20)	
Evening Fatigue (LFS) High \geq 5.6	4.3 (2.3)	70.0 (42)	3.1 (1.7)	30.0 (18)	6.9 (0.8)	30.0 (18)	

Abbreviations: CES-D = Center for Epidemiological Studies - Depression, GSDS = General Sleep Disturbance Scale, LFS = Lee Fatigue Scale, SD = standard deviation, STAI-S = Spielberger State Anxiety Inventory, STAI-T = Spielberger Trait Anxiety Inventory

Table 3

Correlations among the symptom severity scores for depression, anxiety, pain, sleep disturbance, and fatigue

	Depression	Trait Anxiety	State Anxiety	Worst Pain	Sleep Disturbance	Morning Fatigue	Evening Fatigue
Depression	1	.75 < 0.0001 n = 58	.78 < 0.0001 n = 58	.22 0.10 n = 58	.31 0.02 n = 58	.44 < 0.0001 n = 58	.23 0.08 n = 58
Trait Anxiety		1	.69 < 0.0001 n = 58	.35 0.01 n = 59	.33 0.01 n = 59	.48 < 0.0001 n = 59	.20 0.12 n = 59
State Anxiety			1	.14 0.30 n = 59	.30 0.02 n = 59	.44 < 0.0001 n = 59	.18 0.18 n = 59
Worst Pain				1	.30 0.02 n = 60	.35 0.01 n = 60	.23 0.08 n = 60
Sleep Disturbance					1	.44 < 0.0001 n = 60	.43 < 0.0001 n = 60
Morning Fatigue						1	.54 < 0.0001 n = 60
Evening Fatigue							1

Significant correlations are in bold

Table 4

Correlations among symptom severity scores and Karnofsky Performance Status score (KPS) and Quality of Life Inventory (QOL-FV) scores

	KPS		QOL-FV			
	Total Score	Physical Subscale	Psychological Subscale	Social Subscale	Spiritual Subscale	
Depression	-0.32 0.02 n = 53	-0.52 < 0.0001 n = 57	-0.69 < 0.0001 n = 54	-0.58 < 0.0001 n = 56	-0.39 0.004 n = 54	
Trait Anxiety	-0.36 0.01 n = 54	-0.42 0.001 n = 58	-0.67 < 0.0001 n = 55	-0.45 < 0.0001 n = 57	-0.32 0.02 n = 55	
State Anxiety	-0.08 0.55 n = 54	-0.39 0.002 n = 58	-0.66 < 0.0001 n = 55	-0.48 < 0.0001 n = 57	-0.46 < 0.0001 n = 55	
Worst Pain	-0.39 0.01 n = 60	-0.42 0.001 n = 59	-0.28 0.04 n = 56	-0.21 0.12 n = 58	-0.03 0.83 n = 56	
Sleep Disturbance	-0.32 0.02 n = 55	-0.42 0.0001 n = 59	-0.36 0.007 n = 56	-0.34 0.009 n = 58	-0.16 0.24 n = 56	
Morning Fatigue	-0.28 0.04 n = 55	-0.66 < 0.0001 n = 59	-0.59 < 0.0001 n = 56	-0.52 < 0.0001 n = 58	-0.28 0.04 n = 56	
Evening Fatigue	-0.08 0.55 n = 55	-0.55 < 0.0001 n = 59	-0.28 0.04 n = 56	-0.27 0.04 n = 58	.06 0.66 n = 56	

Significant correlations are in bold

Figure 1

For each symptom, differences in Karnofsky Performance Status (A) and total Quality of Life (B) scores between family caregivers in the low and high symptom groups are shown. Values are expressed as means and standard deviations. The * represents significant differences between the groups at a p-value of ≤ 0.05 .

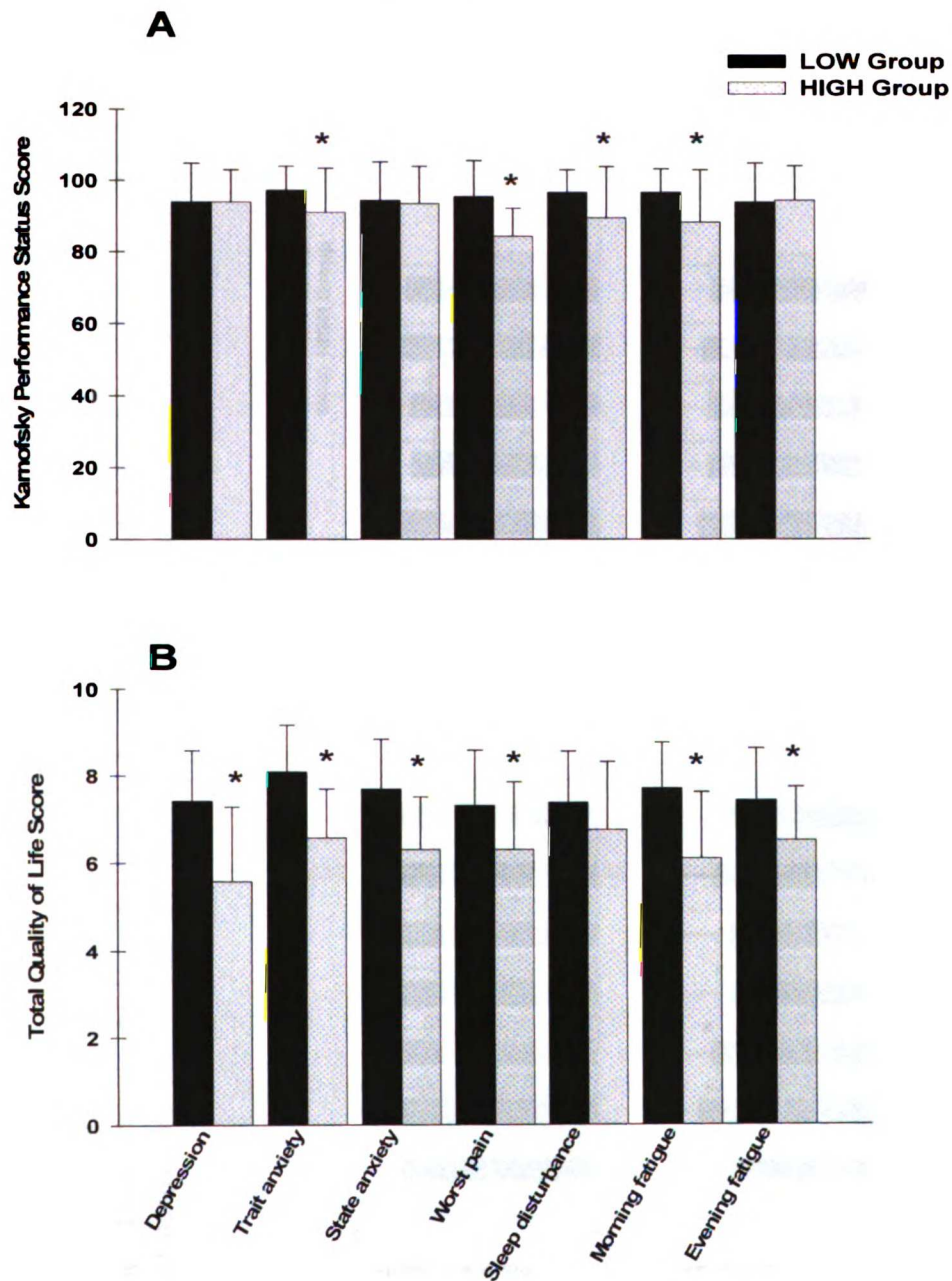
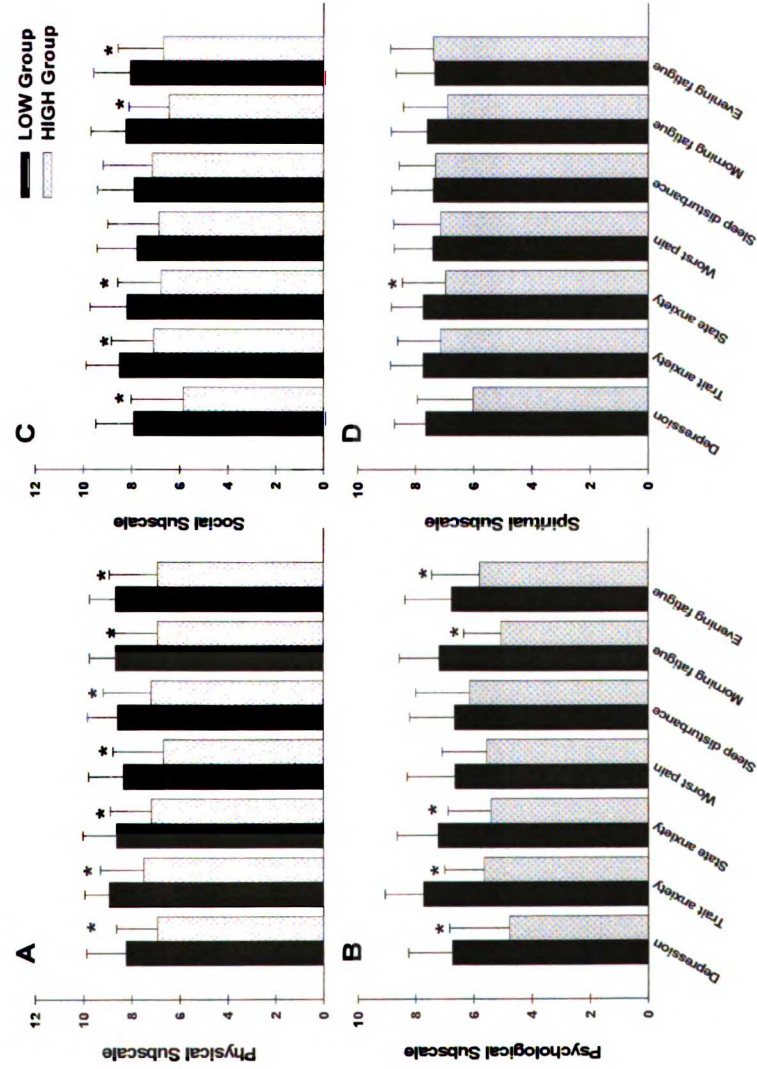
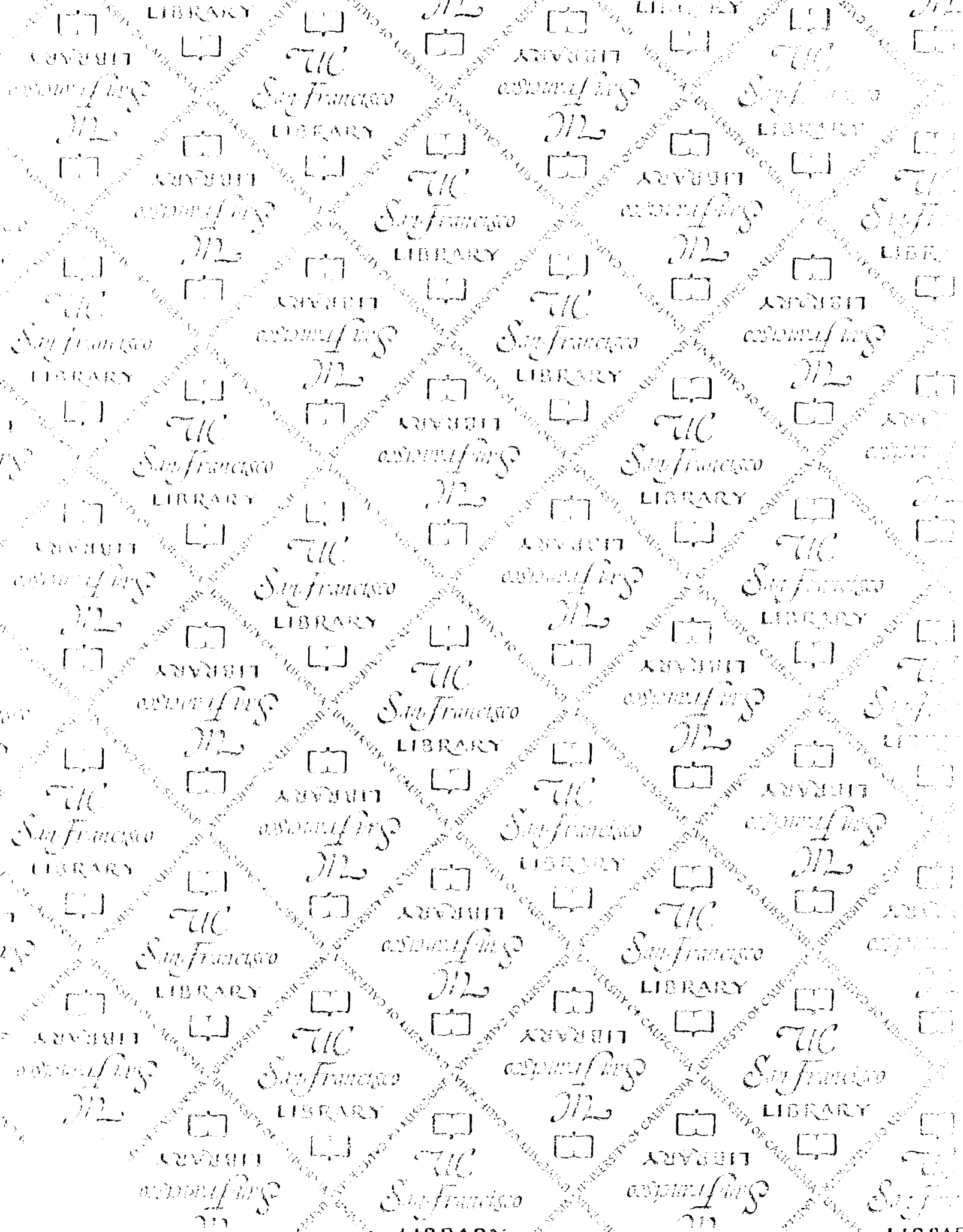


Figure 2

For each symptom, differences in the physical (A), psychological (B), social (C), and spiritual (D) subscale scores of the Quality of Life Scale – Family Version between family caregivers in the low and high symptom groups are shown. Values are expressed as means and standard deviations. The * represents significant differences between the groups at a p-value of ≤ 0.05 .



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