

# The Effects of a Patient-Caregiver Education and Follow-Up Program on the Breast Cancer Caregiver Strain Index

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## Abstract

**Background:** In recent years, the caregiving responsibilities of cancer patients' family members have increased dramatically. Reducing caregiver strain and burden supports the mission of professional nursing.

**Objectives:** The aim of this study was to determine and compare the caregiver strain index scores of breast cancer informal caregivers, before and after a patient-caregiver educational and telephone follow-up program.

**Patients and Methods:** This is an experimental two-group design study. Participants were recruited from an outpatient chemotherapy unit of the largest hematology and oncology research center in Northwest Iran. Thirty patient-caregiver pairs were randomly allocated to intervention and control groups. The intervention group received 2 face-to-face education sessions at bedside and 4 subsequent telephone follow-up sessions. The control group received routine care. Pre and post tests were administered in both groups pre and post intervention. To analyze the data, SPSS (13th version) software was used.

**Results:** The caregiver strain index decreased significantly in the intervention group after the patient-caregiver education and follow-up ( $P < 0.001$ ), while the control group's scores did not change ( $P = 0.04$ ).

**Conclusions:** It appears that the patient-caregiver education and follow-up program had a beneficial effect on the caregiver strain index compared to the usual care.

**Keywords:** Caregivers, Education, Breast Cancer, Strain

## 1. Background

Cancer is the leading cause of death in developed countries and the second-leading cause of death in developing countries. The burden of cancer is increasing in economically developing countries as a result of population aging and growth as well as the adoption of a cancer-associated lifestyle, including smoking, physical inactivity, and Westernized diets (1).

Although patients are directly affected by cancer, all family members are involved as well. The diagnosis can lead to major changes in family status, which should be accepted by families or couples. In any stage of the disease, the family confronts major challenges that can threaten their relationships and quality of life. It is generally accepted that cancer is a family affair. Not only the patient, but everybody who loves him/her also faces the consequences of the disease and treatment, which may include disruptions to their daily lives, anxiety, fears about cancer recurrence, and fears of loss and death (2-8).

On the other hand, family caregivers have psychosocial needs, including caregiver strain, that must be addressed so they can maintain their own health and provide the best care

possible to patients (9-12). In a comparative study by Kim and Schulz, it was revealed that cancer caregiving produces even more strain than dementia and frail elderly caregiving (13).

In recent years, the caregiving responsibilities of cancer patients' family members have increased dramatically, primarily because of the use of toxic treatments in outpatient settings, the decline in available healthcare resources, and the shortage of healthcare providers. In addition, family caregivers of cancer patients have participated in a limited number of intervention programs, but these programs have focused almost exclusively on improving patient outcomes (e.g., symptom management, quality of life) with less attention directed toward the needs of family caregivers. Family caregivers have psychosocial needs that must be addressed so they can maintain their own health and provide the best care possible to patients (14).

One of the key concepts discussed in the context of patient care is caregiver role strain, which means feelings of being overwhelmed by difficulties in performing the role of a care provider and the responsibilities associated with it, impairing their physical or mental health in some way (15).

Reducing caregiver strain and burden supports the mission of professional nursing through efforts to improve the quality of life and other health outcomes for patients with cancer and their caregivers (16).

Despite the fact that a cancer diagnosis can cause major changes in family roles and functioning, as well as an increased responsibility for complex care being absorbed by family caregivers, data supporting the effectiveness of caregiver interventions have been limited (17).

Although generally the role of family caregivers of cancer patients is viewed as important, little is known about the consequences of this role (18).

In addition, despite the crucial role and heavy burden of the family in the care of patients with cancer, the family has rarely been considered in clinical trials (19-21). In a systematic review by Honea et al. (2008), it was revealed that although caregiver burden has recently attracted considerable attention in the literature, a limited number of studies addressing interventions for caregiver strain and burden have been done in oncology (16).

Northouse and her colleagues in a meta-analysis investigated the clinical trials on cancer patients' caregivers conducted during the last 25 years. They found that many of the interventions were designed to address primarily patient care (22).

## 2. Objectives

The aim of this study was to determine and compare the caregiver strain scores of breast cancer informal caregivers, before and after a patient-caregiver educational and telephone follow-up program.

## 3. Patients and Methods

This is an experimental two-group design study. Participants were recruited from an outpatient chemotherapy unit of the largest hematology and oncology research center in Northwest Iran from July 2012 to February 2013. Study approval was received from a university institutional review board (number: 5/55/2157). Informed consent was obtained from each patient included in the study, and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

Participants were the caregivers of breast cancer patients referred to the Hematology and Oncology Research Center of Tabriz University of Medical Sciences, which is the largest governmental cancer center that patients are referred to from the west and northwest areas. Inclusion criteria were the ability to read and write in Persian, not being one of the medical team members, no psychiatric history, and not engaging in a support group. The convenience sampling method was used for the recruitment of participants. From 150 patient-caregivers who were assessed for eligibility, 84 were excluded due to not meeting the inclusion criteria and 6 were excluded due to their lack of interest in participating in the study.

Using the convenient sampling method, all breast cancer

patients referring to the mentioned center were assessed. Eligible patients willing to participate were randomly assigned to either the intervention or control group. To conceal the allocation, opaque-closed envelopes with either the intervention or control name in them were used. The envelopes were prepared by someone other than the researcher. The first envelope was allocated to the first participant and continued until the required sample size was reached.

To assess caregiver strain, we used a caregiver strain index questionnaire that includes 12 items with yes or no responses. It is one of the shortest and simplest questionnaires to use for clinical investigations. To determine the reliability of the questionnaire, we used the test-retest method. Twenty caregivers of breast cancer patients completed it at baseline and then again 3 weeks later. Using the Pearson correlation test, the reliability was calculated ( $R = 0.7$ ).

We asked participants to mark each item that applies to him/her. Each yes answer has a positive number (yes = 1) and no is scored as zero (No = 0).

The total tension score is calculated by summing all positive numbers. According to Robinson, a score of 7 or higher indicates a high level of stress, and a positive answer to each item may indicate a need for intervention. The internal consistency reliability is high ( $\alpha = 0.86$ ) and the construct validity is supported by correlations with the physical and emotional health of the caregiver and with subjective views of the caregiving situation (23). Participants completed study questionnaires in the treatment setting for the initial data collection (baseline) and after the 6-week follow-up session. To determine the sample size, a comparison of the mean formula was used, but due to a lack of similar studies to extract the mean and SD, the sample size was calculated based on the results of a pilot study. Two groups with the lowest mean difference in caregiver strain scores were chosen to calculate the maximum sample size. Considering a mean difference of at least 20%,  $\alpha = 0.05$ , and power = 80%, a required sample of 30 patient-caregiver pairs in each group we estimated 30 pairs for each group. Finally at a 5% statistical significance level and with a power of 80%, 60 patient-caregiver pairs (30 paired in each group) were included in the study (Figure 1).

Both groups received the usual preparation, which included being told that medications would be given on specific days, which side effects might occur, and which medication should be taken to control the side effects.

Education was delivered to the intervention group by the main investigator (a nurse with at least 2 years' experience working in an oncology ward). Generally, the intervention group received 2 personal training sessions and 4 telephone follow-up sessions consecutively. After a pretest, patients and caregivers received the first face-to-face education session simultaneously at bed on self-care, which last for 30 - 45 minute. At the end of the first session, a booklet containing patients' informational needs, such as nutrition, rest and activity, and common chemotherapy side-effect management was given to the dyad. Both patients

and caregivers were encouraged to study the booklet, and the next session (usually 3 weeks later) was scheduled. Forty-eight hours after the first training session, a phone call was conducted to ensure the proper understanding and application of verbal and written instructions as well as an opportunity to ask any possible questions or express their feelings, concerns, and fears. Each patient and caregiver received 3 more telephone follow-up calls for about 10 min weekly after the second personal education.

The content of the booklet included Persian resources on cancer and chemotherapy care introduced by the health ministry and written at a simple and understandable reading level. It was also matched and compared with some English-language handbooks in this field to be comprehensive. An oncologist supervised and confirmed the accuracy of the information. In the second session, the rest of the material was explained using simple language.

As noted previously, the control group received the usual care, and following completion of the study, they were given a copy of the booklet and time to ask any possible questions. Six weeks after the pretest, a posttest was administered by an oncology nurse rather than the investigator. Data were analyzed using SPSS (13 version) software. The assumption of normality of the data was evaluated and confirmed using a one-sample Kolmogorov-Smirnov test for each group. The values are presented as mean  $\pm$  SD for quantitative variables and numbers (percentage) for qualitative variables. Data

on the demographics and disease characteristics for all patients were compared using the Chi-square test, Fisher's exact test, and the independent sample t-test to confirm the matching of the groups. A paired t-test was used to compare mean caregiver strain scores pre and post intervention. P-values of less than 0.05 were considered significant.

## 4. Results

A total of 60 patient-caregiver pairs were recruited in the study. Most of the participants were 30- to 50-year-old, self-employed husbands with a high school education. The Chi-square results revealed that there was no significant statistical difference between the groups regarding demographic characteristics (Table 1).

An independent t-test shows that caregiver strain scores of the two groups were not significantly different pre intervention ( $P = 0.4$ ). However, T-test results indicate that both intervention and control groups in terms of caregiver strain score were statistically different after the intervention ( $P < 0.001$ ) (Table 2).

The mean caregiver strain score of the intervention group was  $8.3 \pm 2$ , and it dropped to  $4.8 \pm 2.3$  post intervention. The paired t-test showed that there is a significant difference pre and post intervention ( $P < 0.001$ ), but no statistically significant difference for the control group ( $P = 0.6$ ) (Table 3).

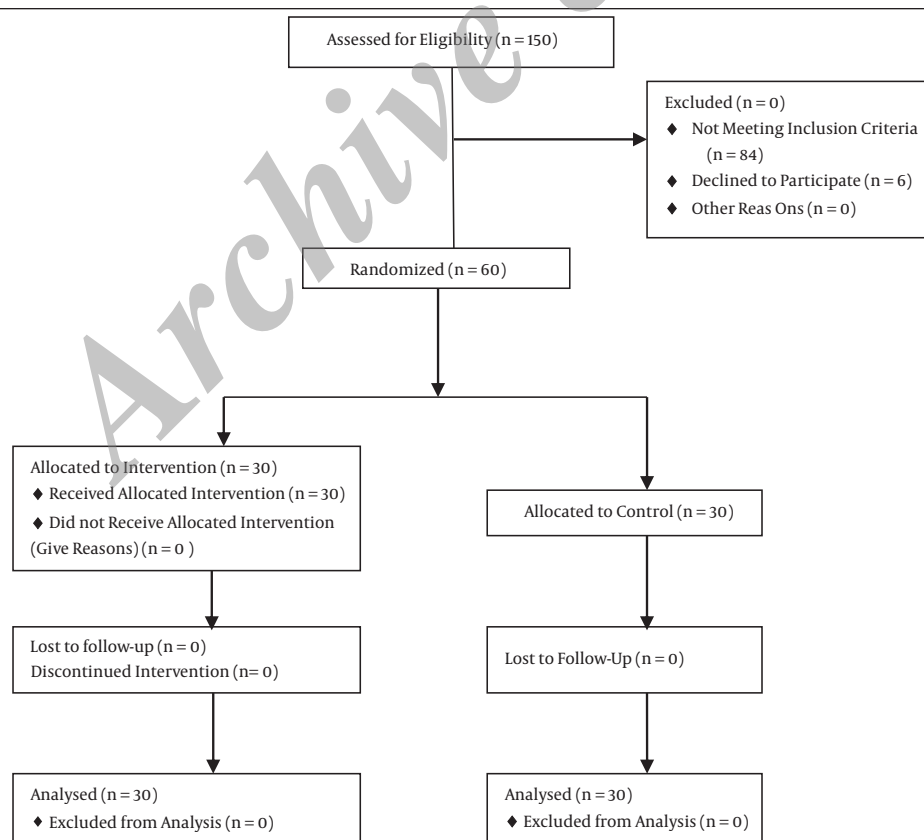


Figure 1. Flow Diagram of the Study

**Table 1.** Demographic Characteristics of Caregivers Participating in the Study (N = 30)<sup>a</sup>

Demographic characteristics	Intervention	Control	Total Scores	Statistical Indicators		
				$\chi^2$	df	P
<b>Age, y</b>				2.15	2	.34
> 30	6 (20)	11 (36.7)	17 (28.3)			
30 - 50	14 (46.7)	12 (40)	26 (43.3)			
< 50	10 (33.3)	7 (23.3)	17 (28.3)			
<b>Education</b>				0.18	3	.98
Primary	6 (50)	6 (50)	12 (20)			
Secondary	8 (50)	8 (50)	16 (27.7)			
High school	13 (52)	12 (48)	25 (41.7)			
University	3 (42.9)	4 (57.1)	7 (11.7)			
<b>Job</b>				6.65	6	.15
Jobless	2 (6.7)	7 (23.3)	9 (15)			
Employee	4 (13.3)	2 (6.7)	6 (10)			
Self-employed	9 (30)	12 (40)	21 (35)			
Housewife	13 (43.3)	6 (20)	19 (31.7)			
Retired	2 (6.7)	3 (10)	5 (8.3)			
<b>Relationship</b>				7.70	7	.35
Husband	13 (43.3)	12 (40)	25 (41.7)			
Daughter	7 (23.3)	7 (23.3)	14 (23.3)			
Son	0	5 (16.7)	5 (8.3)			
Sister	4 (13.3)	4 (13.3)	8 (13.3)			
Brother	1 (3.3)	0	1 (1.7)			
Parents	2 (6.7)	1 (3.3)	3 (5)			
In-laws	1 (3.3)	0	1 (1.7)			
Other	2 (6.7)	1 (3.3)	3 (5)			

<sup>a</sup>Data are presented as No. (%).**Table 2.** Comparison of Caregiver Strain Scores Pre and Post Intervention in the Two Groups<sup>a</sup>

Caregiver Strain	Intervention	Control	Statistical Indicators		
			T <sup>b</sup>	df	P
<b>Pre intervention</b>	8.3 ± 2	7.9 ± 2.2	0.7	58	.4
<b>Post intervention</b>	4.8 ± 2.3	7.8 ± 2.8	-4.5	58	.001

<sup>a</sup>Data are presented as mean ± SD.<sup>b</sup>Independent samples t-test.**Table 3.** Comparison of Caregiver Strain Score Changes Pre and Post Intervention in the Two Groups<sup>a</sup>

Caregiver Strain	Pre Intervention	Post Intervention	Statistical Indicators		
			T <sup>b</sup>	df	P
<b>intervention</b>	4.8 ± 2.3	8.3 ± 2	7.6	29	.001
<b>control</b>	7.8 ± 2.8	7.9 ± 2.2	0.43	29	.67

<sup>a</sup>Data are presented as mean ± SD.<sup>b</sup>Independent samples t-test.



## 5. Discussion

In the present study, the caregiver strain index decreased significantly in the intervention group after the patient-caregiver education and follow-up program ( $P < 0.001$ ), while the control group did not change. In a systematic review, Regan and colleagues emphasized that most of the couple-based interventions included in their review demonstrated significant improvements regarding psychological distress for intervention couples compared to control couples (24). In addition, in a randomized clinical trial, Northouse et al. investigated the effects of a family intervention on prostate cancer patients and their spouses. They applied a "focus" strategy by trained nurses during home visits to involve families in teaching sessions. The results revealed positive outcomes, including a less negative appraisal of caregiving (25).

In a randomized clinical trial, Kurtz and his colleagues tested the effect of a nursing intervention focusing on teaching family caregivers and their cancer patients skills to better manage patients' symptoms (26). However, the intervention was not effective in reducing caregiver depression over the 20-week course of the study, which is inconsistent with the present study, perhaps due to differences in the intervention details (having followed up by telephone and integrated education in the present study) or different stages of the disease; 2.3 of the participants in their study (67%) were in the late stages of the disease, but in our study, most patients were at the beginning of the first cycle of chemotherapy.

In 2007, Walsh and colleagues examined the effects of an intervention on reducing emotional distress in people caring for patients receiving specialist palliative care (27). They also could not identify any benefit in reducing emotional distress (caregiver strain as a second outcome) after six visits over a 6-week period. The main difference is that in their study, the advisors aimed to meet with the caregiver alone, but we conducted a patient-caregiver intervention, which is consistent with Porter et al. suggestion that any intervention involving both patients and caregivers in the training process may reduce caregiver strain (28).

In summary, it appears that the patient-caregiver education and follow-up program had a beneficial effect on the caregiver strain index compared to the usual care. This study is one of several using patient-caregiver education methods simultaneously. However, the generalizability of the results may be limited by the relatively short intervention period and the decision to recruit newly diagnosed cancer patients as participants. We recommend further research to explore whether a delayed follow-up might reveal delayed positive effects of such interventions. Further studies are also required to determine if this kind of intervention can be effective for patients in late stages of the disease.

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## Footnotes

**Authors' Contribution:** Zahra Kochaki Nejad is responsible for the study concept and design, the acquisition of data, the drafting of the manuscript, and the critical revision of the manuscript for important intellectual content. Hadi Hassankhani and Zahra Kochaki Nejad is responsible mainly for the analysis and interpretation of the data. All authors are responsible for the administrative, technical, and material support as well as the study's supervision.

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## References

1. Jemal A, Bray F, Center MM, Ferlay J, Ward E, Forman D. Global cancer statistics. *Cancer J Clin*. 2011;**61**(2):69-90. doi: 10.3322/caac.20107.
2. Bevens M, Sternberg EM. Caregiving burden, stress, and health effects among family caregivers of adult cancer patients. *JAMA*. 2012;**307**(4):398-403. doi:10.1001/jama.2012.29. [PubMed: 22274687]
3. Hagedoorn M, Kreicbergs U, Appel C. Coping with cancer: The perspective of patients' relatives. *Acta Oncol*. 2011;**50**(2):205-11. doi:10.3109/0284186X.2010.536165. [PubMed: 21231782]
4. Cameron JI, Franche RL, Cheung AM, Stewart DE. Lifestyle interference and emotional distress in family caregivers of advanced cancer patients. *Cancer*. 2002;**94**(2):521-7. doi: 10.1002/cncr.10212. [PubMed: 11900237]
5. Nijboer C, Tempelaar R, Sanderma R, Triemstra M, Spruijt RJ, van den Bos GA. Cancer and caregiving: the impact on the caregiver's health. *Psychooncology*. 1998;**7**(1):3-13. doi: 10.1002/(SICI)1099-1611(199801/02)7:1<3::AID-PON320>3.0.CO;2-5. [PubMed: 9516646]
6. Nijboer C, Triemstra M, Tempelaar R, Sanderma R, van den Bos GA. Measuring both negative and positive reactions to giving care to cancer patients: psychometric qualities of the Caregiver Reaction Assessment (CRA). *Soc Sci Med*. 1999;**48**(9):1259-69. [PubMed: 10220024]
7. Fletcher KA, Lewis FM, Haberman MR. Cancer-related concerns of spouses of women with breast cancer. *Psychooncology*. 2010;**19**(10):1094-101. doi:10.1002/pon.1665. [PubMed: 20014184]
8. Carlson LE, Bultz BD, Specia M, St. Pierre M. Partners of Cancer Patients. *J Psychosoc Oncol*. 2008;**18**(2):39-63. doi: 10.1300/J077V18n02\_03.
9. Kagawa-Singer M, Wellisch DK. Breast cancer patients' perceptions of their husbands' support in a cross-cultural context. *Psychooncology*. 2003;**12**(1):24-37. doi:10.1002/pon.619. [PubMed: 12548646]
10. Panganiban-Corales AT, Medina Jr MF. Family resources study: part 1: family resources, family function and caregiver strain in childhood cancer. *Asia Pac Fam Med*. 2011;**10**(1):14. doi: 10.1186/1447-056X-10-14. [PubMed: 22040272]
11. Taleghani F, Yekta ZP, Nasrabadi AN, Kappeli S. Adjustment process in Iranian women with breast cancer. *Cancer Nurs*. 2008;**31**(3):E32-41. doi: 10.1097/01.NCC.0000305720.98518.35. [PubMed: 18453870]
12. Dalvandi A, Khankeh HR, Ekman SL, Maddah SSB, Heikkilä K. Everyday Life Condition in Stroke Survivors and Their Family Caregivers in Iranian Context. *Int J Commun Based Nurs Midwifery*. 2013;**1**(1):3-15.
13. Kim Y, Schulz R. Family caregivers' strains: comparative analysis of cancer caregiving with dementia, diabetes, and frail elderly caregiving. *J Aging Health*. 2008;**20**(5):483-503. doi: 10.1177/0898264308317533. [PubMed: 18420838]

14. Cochrane BB, Lewis FM. Partner's adjustment to breast cancer: a critical analysis of intervention studies. *Health Psychol.* 2005;**24**(3):327-32. doi: 10.1037/0278-6133.24.3.327. [PubMed: 15898870]
15. Ashing-Giwa KT, Padilla G, Tejero J, Kraemer J, Wright K, Coscarelli A, et al. Understanding the breast cancer experience of women: a qualitative study of African American, Asian American, Latina and Caucasian cancer survivors. *Psychooncology.* 2004;**13**(6):408-28. doi:10.1002/pon.750. [PubMed: 15188447]
16. Honea NJ, Brintnall R, Given B, Sherwood P, Colao DB, Somers SC, et al. Putting Evidence into Practice: nursing assessment and interventions to reduce family caregiver strain and burden. *Clin J Oncol Nurs.* 2008;**12**(3):507-16. doi: 10.1188/08.CJON.507-516. [PubMed: 18515250]
17. McCorkle R, Pasacreta JV. Enhancing caregiver outcomes in palliative care. *Cancer Control.* 2001;**8**(1):36-45. [PubMed: 11252271]
18. Rivera Jr HR. *Predictors of cancer caregiver depression symptomatology.* University of South Florida; 2009.
19. Given BA, Given CW, Kozachik S. Family Support in Advanced Cancer. *Cancer J Clin.* 2001;**51**(4):213-31. doi:10.3322/canjclin.51.4.213.
20. Bishop MM, Beaumont JL, Hahn EA, Cella D, Andrykowski MA, Brady MJ, et al. Late effects of cancer and hematopoietic stem-cell transplantation on spouses or partners compared with survivors and survivor-matched controls. *J Clin Oncol.* 2007;**25**(11):1403-11. doi: 10.1200/JCO.2006.07.5705. [PubMed: 17416860]
21. Talley A, Molix L, Schlegel RJ, Bettencourt A. The influence of breast cancer survivors' perceived partner social support and need satisfaction on depressive symptoms: a longitudinal analysis. *Psychol Health.* 2010;**25**(4):433-49. doi: 10.1080/08870440802582682. [PubMed: 20397295]
22. Northouse LL, Katapodi MC, Song L, Zhang L, Mood DW. Interventions with family caregivers of cancer patients: meta-analysis of randomized trials. *CA Cancer J Clin.* 2010;**60**(5):317-39. doi: 10.3322/caac.20081. [PubMed: 20709946]
23. Robinson BC. Validation of a Caregiver Strain Index. *J Gerontol.* 1983;**38**(3):344-8. [PubMed: 6841931]
24. Regan TW, Lambert SD, Girgis A, Kelly B, Kayser K, Turner J. Do couple-based interventions make a difference for couples affected by cancer? A systematic review. *BMC Cancer.* 2012;**12**:279. doi: 10.1186/1471-2407-12-279. [PubMed: 22769228]
25. Northouse LL, Mood DW, Schafenacker A, Montie JE, Sandler HM, Forman JD, et al. Randomized clinical trial of a family intervention for prostate cancer patients and their spouses. *Cancer.* 2007;**110**(12):2809-18. doi:10.1002/cncr.23114. [PubMed: 17999405]
26. Kurtz ME, Kurtz JC, Given CW, Given B. A randomized, controlled trial of a patient/caregiver symptom control intervention: effects on depressive symptomatology of caregivers of cancer patients. *J Pain Symptom Manage.* 2005;**30**(2):112-22. doi: 10.1016/j.jpainsymman.2005.02.008. [PubMed: 16125026]
27. Walsh K, Jones L, Tookman A, Mason C, McLoughlin J, Blizard R, et al. Reducing emotional distress in people caring for patients receiving specialist palliative care. Randomised trial. *Br J Psychiatry.* 2007;**190**:142-7. doi: 10.1192/bjp.bp.106.023960. [PubMed: 17267931]
28. Porter LS, Keefe FJ, McBride CM, Pollak K, Fish L, Garst J. Perceptions of patients' self-efficacy for managing pain and lung cancer symptoms: correspondence between patients and family caregivers. *Pain.* 2002;**98**(1-2):169-78. [PubMed: 12098629]