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Randomized Pilot Trial of a Telephone Symptom Management Intervention for Symptomatic Lung Cancer Patients and Their Family Caregivers

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Abstract

Context—Lung cancer is one of the most common cancers affecting both men and women and is associated with high symptom burden and psychological distress. Lung cancer patients' family caregivers also show high rates of distress. However, few interventions have been tested to alleviate significant problems of this population.

Objectives—This study examined the preliminary efficacy of telephone-based symptom management (TSM) for symptomatic lung cancer patients and their family caregivers.

Methods—Symptomatic lung cancer patients and caregivers (N=106 dyads) were randomly assigned to 4 sessions of TSM consisting of cognitive-behavioral and emotion-focused therapy or an education/support condition. Patients completed measures of physical and psychological symptoms, self-efficacy for managing symptoms, and perceived social constraints from the caregiver; caregivers completed measures of psychological symptoms, self-efficacy for helping the patient manage symptoms and managing their own emotions, perceived social constraints from the patient, and caregiving burden.

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Disclosures

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Results—No significant group differences were found for all patient outcomes and caregiver self-efficacy for helping the patient manage symptoms and caregiving burden at 2 and 6-weeks post-intervention. Small effects in favor of TSM were found regarding caregiver self-efficacy for managing their own emotions and perceived social constraints from the patient. Study outcomes did not significantly change over time in either group.

Conclusion—Findings suggest that our brief telephone-based psychosocial intervention is not efficacious for symptomatic lung cancer patients and their family caregivers. Next steps include examining specific intervention components in relation to study outcomes, mechanisms of change, and differing intervention doses and modalities.

Keywords

lung cancer; family caregivers; psychosocial interventions; cognitive-behavioral; symptom management; distress

Introduction

Lung cancer is one of the most frequently diagnosed cancers and the leading cause of cancer deaths in both men and women.[1] Most lung cancer patients (85%) have regional or distant metastases at diagnosis, contributing to their high rate (80%) of multiple physical and psychological symptoms.[2–4] Lung cancer patients experience higher rates of anxiety and depressive symptoms and breathlessness than other cancer patients.[5–7] The most frequent and severe symptoms in lung cancer patients include depression, anxiety, pain, fatigue, and breathlessness, which contribute to impaired quality of life (QoL).[2, 8–11] Greater distress and reduced QoL in lung cancer patients have been associated with lower self-efficacy or confidence in their ability to manage symptoms and greater social constraints (e.g., avoidance, criticism) on cancer-related disclosure.[12, 13]

Family caregivers' QoL is also affected.[14–18] Up to 50% of family caregivers of lung cancer patients experience significant anxiety or depressive symptoms.[14, 19–22] Greater caregiver distress has been related to greater caregiving burden and lower self-efficacy in assisting the patient with symptom management.[12, 23] Caregivers of lung cancer patients have reported difficulty with caregiving tasks such as providing emotional support and monitoring symptoms.[24, 25]

Clinical practice guidelines for lung cancer have changed to emphasize the early integration of standard oncologic and palliative care based on evidence that this may improve QoL and possibly survival in advanced lung cancer patients.[26–28] Although palliative care services are available in many hospitals, patients with lung and other cancers and their caregivers have reported high rates of unmet needs for symptom management and psychosocial support.[29–31] In addition, non-pharmacologic aspects of palliative care have a limited evidence base for use with lung cancer patients and caregivers.[32–34] To date, cognitive-behavioral interventions have reduced physical symptom severity in patients with various cancers and chronic illnesses[35–41] and reduced distress in primarily early-stage cancer patients and caregivers.[32, 38] Two trials have tested emotion-focused interventions for couples coping with cancer and both showed improved relational outcomes.[42, 43] Regarding trials specific to lung cancer patients and caregivers, one pilot study found that a telephone-based dyadic intervention reduced advanced lung cancer patient and caregiver anxiety and depressive symptoms and caregiver burden compared to usual care.[44] A telephone-based trial for early-stage lung cancer patients and caregivers found that both caregiver-assisted coping skills training and education/support led to improvement in patient depression, lung cancer symptoms, and self-efficacy for symptom control as well as caregiver anxiety and self-efficacy for helping the patient manage symptoms.[45]

The present study tested a novel telephone-based symptom management (TSM) intervention with lung cancer patients and caregivers jointly participating. Telephone delivery reduces barriers to participation for people with physical impairments. While most prior symptom management trials with cancer patient-caregiver dyads have emphasized patient care,[32, 45–49] TSM has a dual focus on patient and caregiver concerns. The intervention involves a blend of evidence-based cognitive-behavioral and emotion-focused strategies[42, 45, 50–53] to address patient and caregiver anxiety and depressive symptoms and patient pain, fatigue, and breathlessness. These primary outcomes were chosen because they are amenable to non-pharmacologic intervention and prevalent in this population.[2, 8–11, 14, 22] The intervention was framed by Social Cognitive Theory, which hypothesizes that self-efficacy to implement symptom management strategies will result in improved health outcomes.[54, 55] The TSM intervention was designed to influence self-efficacy by encouraging practice of new skills, emphasizing the benefits of practicing the skills, and changing maladaptive thoughts. Self-efficacy also may be enhanced as patients and caregivers reinforce each other’s practice of the skills.

We enrolled lung cancer patients who met clinical criteria for at least one of five symptoms targeted in the intervention (i.e., depressive symptoms, anxiety, pain, fatigue, or breathlessness) and their family caregivers. We hypothesized that TSM would lead to improved primary outcomes for patients (i.e., reduced depressive symptoms, anxiety, pain, fatigue, and breathlessness) and caregivers (i.e., reduced depressive symptoms and anxiety) as compared to an education/support condition that controlled for time and attention provided to participants. We also hypothesized that TSM would lead to improved secondary outcomes for patients (i.e., self-efficacy for symptom management and perceived social constraints from the caregiver) and caregivers (i.e., self-efficacy for helping the patient manage symptoms and managing their own emotions, perceived social constraints from the patient, and caregiving burden) as compared to the education/support condition.

Methods

Participants and Setting

Participants were recruited from the Indiana University Simon Cancer Center, the Roudebush VA Medical Center, and Eskenazi Hospital in Indianapolis, IN between March 2013 and April 2015. All study procedures received institutional review board approval (Clinicaltrials.gov number NCT01993550). Patient inclusion requirements were: 1) a diagnosis of small-cell or non-small-cell lung cancer, 2) English fluency, 3) at least one symptom of moderate severity, defined by validated cutpoints for depressive symptoms (Patient Health Questionnaire-2 [PHQ-2] score ≥ 3 on this 0–6 scale);[56] anxiety

(Generalized Anxiety Disorder two-item scale [GAD-2] score ≥ 3 on this 0–6 scale);[57] pain (PEG score ≥ 5 on this 0–10 scale);[58] fatigue (SF-36 Vitality score ≤ 45 on this 0–100 scale);[59, 60] or breathlessness (Memorial Symptom Assessment Scale [MSAS] shortness-of-breath severity score ≥ 2 on this 1–4 scale),[61] and 4) a consenting family caregiver. Patients were excluded from study participation if they: 1) had severe cognitive impairment defined as four or more errors on a six-item cognitive screener,[62] or 2) were receiving hospice care at the time of enrollment.

An authorized study team member reviewed medical records and consulted with oncologists to confirm initial patient eligibility. A research assistant approached the patient during an oncology clinic visit to describe the study. Interested patients identified their primary family caregiver (i.e., the person who provided most of their unpaid, informal care) and completed the symptom eligibility screening. With the patient's written consent, a research assistant approached caregivers in clinic or via telephone to obtain informed consent. Eligible caregivers were adults (18+ years of age) who were fluent in English and lived with the patient or had visited the patient at least twice a week for the past month. At the time of enrollment, all participants received a brochure outlining psychosocial services at the study site.

Adequate sample size was determined on the basis of group comparisons of anxiety and depressive symptoms. An *a priori* power analysis suggested that a mixed linear model would have 80% power to detect a Cohen's d of 0.63 (P=0.05, two-sided) in a sample of 42 patient-caregiver dyads, assuming an intraclass correlation coefficient of 0.05.[63] This effect size is smaller than that found for anxiety and depressive symptoms in a trial comparing a dyadic telephone-based psychosocial intervention to usual care for advanced lung cancer patients and caregivers.[44]

Of the 337 potentially eligible lung cancer patients who were approached regarding this study, 86 declined to participate, 117 were deemed ineligible, and 134 consented. The most common reasons for study refusal were lack of interest, time constraints, and personal stress. Most ineligible patients did not meet the symptom criterion for study entry. Of the 134 patients and 128 caregivers who consented, 50 withdrew before randomization primarily because of medical reasons, loss of interest, or an inability to reach them via phone. Thus, 106 patient-caregiver dyads were included in the current analyses (Fig. 1).

Procedures

All participants completed an individual baseline assessment and then patient-caregiver dyads were randomly assigned to one of two conditions: 1) telephone symptom management (TSM; n=51 dyads) or 2) an education/support condition (n=55 dyads). Randomization assignments were generated by a person who was not a study interviewer or therapist using a SAS procedure. Randomization was stratified by patient gender and performance status (self-reported Eastern Cooperative Oncology Group scores 0 or 1 vs. ≥2).[64, 65] Patients and caregivers completed an individual follow-up assessment at 2 weeks and 6 weeks post-intervention because we were interested in short-term effects of the intervention and two weeks matched the time frame of certain measures. Research assistants who were blind to study condition conducted all assessments via telephone.

General Aspects of Treatment Procedures and Therapist Training—Participants in both study conditions (TSM and education/support) participated in four weekly 45-minute telephone sessions. Both dyad members participated simultaneously via speakerphone, and all sessions were audiorecorded. Both study conditions were delivered by licensed clinical social workers who were trained by a PhD-level psychologist. Training included didactic instruction and role-plays of treatment sessions detailed in manuals. Following the initial training, social workers received weekly supervision from the psychologist who reviewed 53% of audiorecordings for adherence to the study protocol and provided feedback on treatment adherence and quality. The average fidelity rating was 97.5%.

Telephone Symptom Management—Participants in this condition received instruction in symptom management strategies. Each person was mailed identical handouts detailing major points discussed during the sessions and home practice assignments as well as a CD with instructions for relaxation exercises. The primary goal of the intervention was to teach patients and caregivers various evidence-based cognitive-behavioral and emotion-focused strategies for managing anxiety and depressive symptoms, pain, fatigue, and breathlessness. All sessions had a dual focus on patient and caregiver concerns. A summary of the intervention components appears in Table 1.

During the first session, the social worker introduced the sessions as providing information and skills for coping with lung cancer and discussed cancer-related changes that the patient and caregiver had experienced. During the four sessions, the patient and caregiver received instruction in symptom management strategies, including relaxation exercises, problem-solving, cognitive restructuring, emotion-focused/self-soothing approaches, communication skills, pleasant activity scheduling, and activity pacing. The symptoms endorsed by the patient or caregiver were emphasized when presenting the strategies, but all dyads received training in the same strategies. Skill practice comprised the majority of each session, and dyad members practiced the skills simultaneously (e.g., relaxation) or consecutively (e.g., communication). Each session began with a review of the patient’s and caregiver’s practice of the skills and ended with a discussion of a home practice assignment. Dyad members were encouraged to practice the skills together at home.

Education/Support Condition—The primary goal of this intervention was to direct participants to resources for practical and health information and psychosocial services. A similar comparison group was used in a prior psychosocial intervention trial with gastrointestinal cancer patients and caregivers.[43] The therapists were the same as those for the TSM condition. Table 1 provides a summary of the intervention components. The sessions included the following topics: orientation to the medical center and treatment team, the impact of cancer on QoL, resources for health information, psychosocial support, and financial concerns, and evaluating health information on the Internet. Each person was mailed handouts summarizing the topics for each session and was asked to review them at home. Instruction in symptom management strategies did not occur in the education/support condition.

Measures

The primary and secondary outcomes were assessed with validated self-report measures used with cancer patients and caregivers.

Primary Outcomes—The Patient Health Questionnaire-8 (PHQ-8)[66, 67] and Generalized Anxiety Disorder seven-item scale (GAD-7)[57] were used to assess patient and caregiver depressive and anxiety symptoms, respectively. In addition, the following measures assessed patient physical symptoms: 1) the Brief Pain Inventory Short Form consisting of pain severity and pain interference subscales;[68, 69] 2) the Fatigue Symptom Inventory consisting of fatigue frequency, severity, and interference subscales;[70, 71] and 3) four items from the MSAS assessing the frequency and severity of breathlessness as well as distress related to breathlessness.[61]

Secondary Outcomes—A 16-item standard self-efficacy scale modified from the arthritis literature was used to assess patients' perceived ability to manage pain, other symptoms, and function.[12, 72] A parallel version of this scale was administered to caregivers to assess their confidence in their ability to help the patient manage symptoms.[12, 72] In addition, eight items developed by Kilbourn et al.[73] were used to assess caregivers' self-efficacy for managing their own emotions. Patients and caregivers also completed the 5-item social constraints scale assessing perceived constraints on cancer-related disclosure from the other dyad member.[74] Finally, the Caregiver Reaction Assessment was used to evaluate caregiver burden and included the following subscales: impact on schedule, caregiver's esteem, lack of family support, impact on health, and impact on finances.[75]

Sociodemographic and Medical Variables—Patients and caregivers reported their demographic information and use of mental health services at baseline. Patient medical information was obtained via chart review.

Statistical Analyses

Baseline comparisons (Fisher's exact tests and *t*-tests) assessed differences between the TSM and education/support groups for patients and caregivers separately. Possible gender differences were examined. Linear mixed-model repeated measures analyses in SPSS were used to examine the preliminary efficacy of TSM. Because these analyses use all available data, an intent-to-treat framework was implemented. For outcomes reported by patients and caregivers, multilevel modeling for dyadic data was used to account for the non-independence of data from two members of the same dyad.[76, 77] Models included the main effects of time, study group, and social role (patient or caregiver) as well as time x group and time x group x role interactions. Both time and study group were treated as categorical variables in these models, which focuses the analyses on mean differences between groups and across time. A significant treatment effect is indicated either by a significant study group main effect or a significant time x group interaction. A significant time x group x role interaction indicates that the treatment effect differs for patients and caregivers. For outcome measures that only patients or caregivers completed, models included main effects of time and study group (TSM or education/support) and the time x group interaction. Again, all variables were treated as categorical. Gender was not included in the models because only two significant gender differences in outcomes were found (data not shown).

Results

Participant Characteristics

Table 2 presents participant characteristics by study group and group comparisons at baseline. About half of the patients (53%) were women, and most caregivers (73%) were women. Patients and caregivers were primarily White and had completed an average of 13 years of education. The median annual household income was over $30,000. Sixty-three percent of caregivers were spouses or partners of the patient. No significant baseline differences on demographic, medical, or outcome variables were found for patients and caregivers randomized to TSM and education/support conditions, with the exception of caregiver income.

Primary Outcomes

Results from the mixed model dyadic analyses revealed no main effect of study group or time x group effect for anxiety and depressive symptoms (Table 3). However, there was a main effect of role on depressive symptoms such that patients, on average, had higher levels of depressive symptoms than caregivers. In addition, mixed model analyses showed no main effects of study group or time x group effect for patient pain, fatigue, or breathlessness (Table 4). There were also no significant main effects of time, indicating that in general primary outcome variables did not change on average over the study period.

Secondary Outcomes

Mixed model analyses revealed no main effects of study group or time x group effect for patient self-efficacy for symptom management or perceived social constraints from the caregiver (Table 4). Regarding secondary outcomes for caregivers, there was a significant time x group effect for self-efficacy for managing their own emotions. Means found in Table 5 showed a small increase in self-efficacy for managing emotions in the TSM group, whereas the mean scores for the education/support group showed a slight decline. In addition, there was a main effect of study group on caregiver reports of perceived social constraints from the patient in favor of TSM (Table 5). Thus, caregivers assigned to TSM felt less constrained in discussing the illness with the patient than those assigned to education/support. In addition, there were no main effects of study group or time x group effect for caregivers’ self-efficacy for managing the patient’s symptoms and all aspects of caregiving burden (Table 5).

Discussion

This study is one of the first to examine a dyadic psychosocial intervention for lung cancer patients and caregivers and to focus on lung cancer patients with clinically meaningful symptoms. Lung cancer patient-caregiver dyads were randomized to four sessions of TSM consisting of evidence-based cognitive-behavioral and emotion-focused therapy or four sessions of an education/support condition. Compared to the education/support condition, TSM did not result in improved patient and caregiver depressive symptoms or anxiety or improved patient pain, fatigue, or breathlessness. In addition, compared to education/support, TSM did not improve patient self-efficacy for managing their symptoms or perceived social constraints from the caregiver. TSM also did not improve caregiver self-efficacy for assisting the patient with symptom management and caregiving burden. In contrast, caregivers assigned to TSM showed better self-efficacy for managing their emotions and decreases in perceived social constraints from the patient across follow-ups; however, the effect sizes were small. Study outcomes did not significantly change over time for either group. Thus, findings do not support the efficacy of our brief telephone-based dyadic psychosocial intervention for symptomatic lung cancer patients and caregivers.

The current results are partially consistent with those of prior intervention studies with this population.[33, 44, 45] For example, Porter and colleagues[45] tested 14 telephone sessions of caregiver-assisted coping skills training or education/support for early-stage lung cancer patients and caregivers and found no differences in psychological distress or symptoms between study conditions. Both groups showed improved outcomes following the intervention. Conversely, another study found large effects of a 6-session telephone dyadic psychosocial intervention on advanced lung cancer patient and caregiver anxiety and depressive symptoms and caregiver burden compared to usual care.[44] Differences in findings across studies may be related to characteristics of the sample, intervention and control groups, and assessments.

Several potential explanations for the current findings warrant consideration. First, brief cognitive-behavioral and emotion-focused therapy may not be sufficient for addressing the high symptom burden and unique challenges of lung cancer patients and caregivers. Similar to the general population of lung cancer patients,[78] participants were, on average, socioeconomically disadvantaged, which may have contributed to suboptimal outcomes and barriers to participation. A meta-analysis found limited and inconclusive evidence that non-pharmacologic interventions impact lung cancer patient outcomes.[33] In addition, meta-analyses have found small effects of couple-based and caregiver-focused interventions on psychological outcomes for cancer patients' caregivers.[32, 34] Thus, this study contributes to a limited but growing literature suggesting that novel approaches are needed to address the significant problems faced by lung cancer patients and caregivers.

Another possible explanation for the current findings is that the brief intervention length and telephone delivery lessened the impact of the intervention. As noted earlier, Porter and colleagues[45] found that lung cancer patients and caregivers assigned to 14 sessions of telephone-based coping skills training or education/support showed improved symptom outcomes over time. Meta-analytic evidence regarding the effect of intervention dose on cancer patient and caregiver outcomes has been mixed.[32, 34] One meta-analysis of individual and dyadic interventions for cancer patients' caregivers found that fewer intervention sessions were associated with lower levels of depression and caregiving burden.[32] Another meta-analysis of couple-based interventions did not find an association between the number of sessions and cancer patient and caregiver outcomes.[34] Further work is needed to determine the optimal intervention dose. With respect to intervention modality, there is no evidence that telephone delivery is inferior to in-person treatment with respect to cancer patient and caregiver psychological outcomes, but few comparisons of different modalities have been conducted.[32]

Finally, this study did not include a usual care group. This group may have shown worsening outcomes over time relative to the TSM and education/support conditions. Three-arm trials are needed which compare new interventions to attention control conditions and usual care. Such trials would allow for more definitive conclusions regarding the impact of interventions.

Results of this study suggest several potential directions for future research. First, examining associations between specific intervention components and outcomes will allow researchers to develop more efficacious interventions. In addition, understanding the mechanisms underlying the effects of interventions will advance the science of symptom management and translation of findings to clinical care. A focus on participants with clinically meaningful symptoms will enhance the generalizability of findings to those who warrant clinical attention. Finally, comparing a dyadic to an individual intervention approach and different intervention modalities will clarify the most feasible and effective approach for this population.

Limitations of this study should be noted. The sample was primarily Caucasian and was recruited from three medical centers in the Midwestern U.S. Thus, the findings may not generalize to ethnic minorities and those in other geographic regions. Additionally, caregivers were eligible for this study regardless of their distress, which may have reduced intervention effects. Furthermore, the attrition rate was 40% at 6 weeks post-intervention, which is comparable to attrition rates in other studies with this population.[45, 79] Finally, the study was underpowered for detecting moderators of the intervention's effects. Further work with larger sample sizes is needed to determine for whom psychosocial interventions are most efficacious.

Our findings suggest that symptomatic lung cancer patients and caregivers may require more intensive intervention to produce symptom reduction. Next steps include examining the effects of specific components of our intervention on outcomes. Identifying the most efficacious approaches for symptom reduction and mechanisms underlying their effects is a critical issue in palliative care for this large, underserved population.

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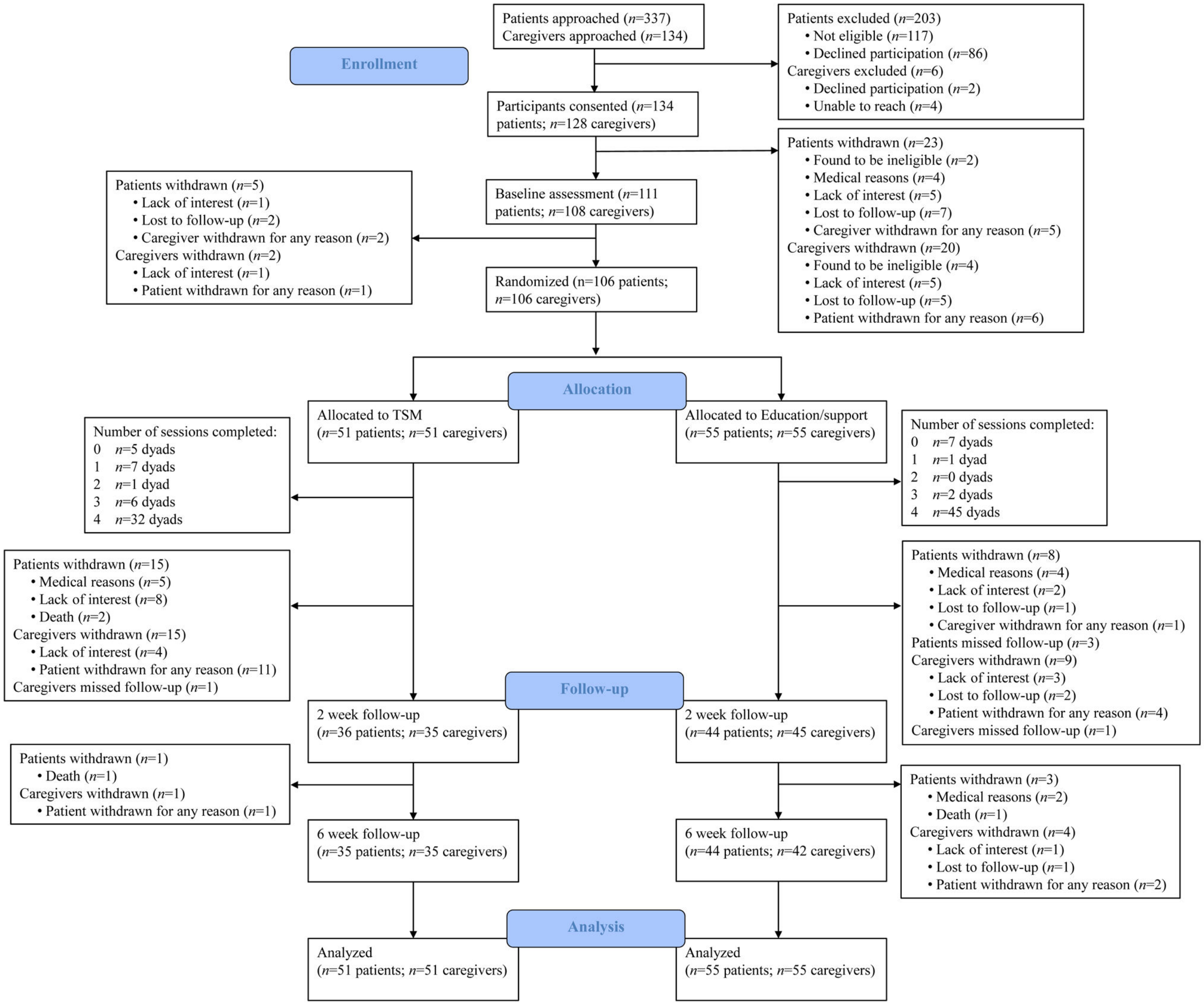

Figure 1.

Study Flow Chart

Table 1

Summary of Topics Covered in Each Intervention Condition

Telephone Symptom Management	**Education/Support**
• Relaxation: – Mindfulness exercise – Imagery – Pursed lips breathing • Cognitive restructuring (for unrealistic thoughts) • Problem-solving (for realistic thoughts about controllable situations) • Self-soothing/emotion-focused approach (for realistic thoughts about uncontrollable situations, such as thoughts of death and dying) • Pleasant activities • Activity pacing • Communication • Plan for continued skills practice	• Orientation to the medical center and the treatment team • Psychoeducation regarding the impact of cancer on quality of life, including physical, social, emotional, and cognitive domains and roles and activities. • Resources for addressing financial concerns • Evaluating health information on the Internet

Table 2

Patient and Caregiver Characteristics and Group Comparisons at Baseline

	Patients (n = 106)			**Caregivers (n = 106)**		
Characteristic	**TSM (n = 51)**	**Education/support (n = 55)**	***t*-test/Fisher's exact test *p***	**TSM (n = 51)**	**Education/support (n = 55)**	***t*-test/Fisher's exact test *p***
Sex, *n* (%)			0.70			0.99
Male	23 (45.10)	27 (49.09)		14 (27.45)	15 (27.27)	
Female	28 (54.90)	28 (50.91)		37 (72.55)	40 (72.73)	
Age			0.33			0.88
Mean	63.47	61.96		56.33	56.75	
SD	7.68	8.20		14.09	13.81	
Range	45–85	42–82		20–76	20–80	
Race, *n* (%)						
non-Hispanic White	45 (88.24)	51 (92.73)	0.52	44 (86.27)	51 (92.73)	0.51
Missing	0 (0.00)	0 (0.00)		1 (1.96)	0 (0.00)	
Household income, *n* (%)						
\$0 – \$20,999	10 (19.61)	10 (18.18)	0.80	8 (15.69)	8 (14.55)	0.79
\$21,000 – \$50,999	12 (23.53)	21 (38.18)	0.20	11 (21.57)	26 (47.27)	0.01
\$51,000 – \$99,999	13 (25.49)	11 (20.00)	0.35	17 (33.33)	9 (16.36)	0.02
\$100,000 or more	7 (13.73)	8 (14.55)	0.99	9 (17.65)	10 (18.18)	0.99
Missing	9 (17.65)	5 (9.09)		6 (11.76)	2 (3.64)	
Employment status, *n* (%)						
Employed full or part-time	9 (17.65)	13 (23.64)	0.48	23 (45.10)	30 (54.55)	0.44
Retired	25 (49.02)	20 (36.36)	0.24	16 (31.37)	15 (27.27)	0.67
Unemployed/other (e.g., sick leave, homemaker)	17 (33.33)	22 (40.00)	0.55	11 (21.57)	10 (18.18)	0.64
Missing	0 (0.00)	0 (0.00)		1 (1.96)	0 (0.00)	
Years of education			0.57			0.35
Mean	12.92	13.16		13.94	13.45	
SD	2.22	2.11		2.85	2.54	
Range	9–19	9–19		8–20	9–19	
Caregiver relationship to the patient, *n* (%)						
Spouse/partner				32 (62.75)	34 (61.82)	0.99

Characteristic	Patients (*n* = 106) TSM (*n* = 51)	Education/support (*n* = 55)	*t*-test/Fisher's exact test *p*	Caregivers (*n* = 106) TSM (*n* = 51)	Education/support (*n* = 55)	*t*-test/Fisher's exact test *p*
Son/daughter				9 (17.65)	12 (21.82)	0.63
Other family member or friend				10 (19.61)	9 (16.37)	0.80
Caregiver lives with the patient, *n* (%)				37 (72.55)	41 (74.55)	0.83
Married/living with partner, *n* (%)	35 (68.63)	37 (67.27)	0.99	41 (80.39)	41 (74.55)	0.50
Psychiatric medication, *n* (%)[1]	22 (43.14)	34 (61.82)	0.08	13 (25.49)	20 (36.36)	0.29
Psychotherapy/counseling, *n* (%)[1]	1 (1.96)	5 (9.09)	0.21	2 (3.92)	1 (1.82)	0.61
Study site, *n* (%)						
Indiana University Simon Cancer Center	39 (76.47)	42 (76.36)	0.99			
Roudebush VA Medical Center	10 (19.61)	10 (18.18)	0.99			
Eskenazi Hospital in Indianapolis	2 (3.92)	3 (5.45)	0.99			
Type of lung cancer, *n* (%)			0.77			
NSCLC	44 (86.27)	49 (89.09)				
SCLC	7 (13.73)	6 (10.91)				
Stage of NSCLC, *n* (%)						
Stage I	12 (23.53)	6 (10.91)	0.11			
Stage II	4 (7.84)	10 (18.18)	0.15			
Stage III	9 (17.65)	9 (16.36)	0.99			
Stage IV	19 (37.25)	24 (43.64)	0.68			
Stage of SCLC, *n* (%)			0.56			
Limited-stage	3 (5.88)	1 (1.82)				
Extensive-stage	4 (7.84)	5 (9.09)				
Time since diagnosis in years			0.65			
Mean	1.26	1.09				
SD	2.12	1.46				
Range	0.07–11.99	0.10–8.52				
Missing, *n* (%)	1 (1.96)	2 (3.64)				
Lung cancer treatments received, *n* (%)						
Chemotherapy	27 (52.94)	34 (61.82)	0.43			
Radiation	13 (25.49)	15 (27.27)	0.99			

	Patients ($n = 106$)			Caregivers ($n = 106$)		
Characteristic	**TSM ($n = 51$)**	**Education/support ($n = 55$)**	***t*-test/Fisher's exact test *p***	**TSM ($n = 51$)**	**Education/support ($n = 55$)**	***t*-test/Fisher's exact test *p***
Chemoradiation	12 (23.53)	11 (20.00)	0.81			
Surgery	24 (47.06)	23 (41.82)	0.70			
Patient self-reported ECOG score			0.65			
Mean	1.43	1.51				
SD	0.92	0.86				
Range	0–3	0–4				
Depressive symptoms, *n* (%)[2]	19 (37.25)	24 (43.64)	0.56			
Anxiety, *n* (%)[2]	20 (39.22)	18 (32.73)	0.55			
Pain, *n* (%)[2]	17 (33.33)	19 (34.55)	0.99			
Fatigue, *n* (%)[2]	27 (52.94)	26 (47.27)	0.70			
Breathlessness, *n* (%)[2]	34 (66.67)	38 (69.09)	0.84			
Number of symptoms[2]			0.93			
Mean	2.29	2.27				
SD	1.17	1.28				
Range	1–5	1–5				

Note. TSM = Telephone-based symptom management intervention; *SD* = standard deviation; NSCLC = non-small cell lung cancer; SCLC = small cell lung cancer; ECOG = Eastern Cooperative Oncology Group.

[1] Treatment received in the past month at baseline.

[2] Symptoms assessed at screening.

Table 3

Intent-to-Treat Results for Multilevel Linear Models Predicting Dyadic Outcomes (n = 106 dyads)

	TSM			**Education/support**					
	Baseline	**2 weeks post-intervention**	**6 weeks post-intervention**	**Baseline**	**2 weeks post-intervention**	**2 weeks post-intervention**			
Outcome **Fixed effect**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	***df***	***F***	***p***
Patient Depressive Symptoms	7.33 (4.78)	6.36 (3.75)	6.71 (4.77)	8.27 (5.48)	8.36 (5.67)	7.18 (5.25)			
Caregiver Depressive Symptoms	5.67 (5.59)	5.09 (4.88)	4.83 (4.90)	5.33 (5.02)	5.89 (5.22)	5.64 (5.67)			
Group							103	0.56	0.45
Time							161	0.32	0.72
Role							106	11.49	0.00
Time X Role							165	0.33	0.72
Group X Time							161	0.69	0.50
Group X Role							106	0.21	0.65
Group X Time X Role							165	1.15	0.32
Patient Anxiety Symptoms	5.12 (4.89)	3.72 (3.45)	4.06 (3.82)	6.31 (5.91)	6.68 (6.48)	5.45 (5.93)			
Caregiver Anxiety Symptoms	6.10 (5.19)	5.06 (4.28)	5.00 (4.77)	6.02 (5.74)	6.51 (6.04)	5.86 (6.25)			
Group							106	2.76	0.10
Time							164	1.78	0.17
Role							104	0.30	0.59
Time X Role							162	0.09	0.92
Group X Time							164	2.58	0.08
Group X Role							104	0.77	0.38
Group X Time X Role							162	0.68	0.51

Note. TSM = Telephone-delivered symptom management intervention; *SD* = standard deviation.

Table 4

Intent-to-Treat Results for Multilevel Linear Models Predicting Patient Outcomes ($n = 106$)

	TSM			Education/support					
	Baseline	2 weeks post-intervention	6 weeks post-intervention	Baseline	2 weeks post-intervention	6 weeks post-intervention			
Outcome **Fixed effect**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	***df***	***F***	***p***
Pain Severity	2.61 (2.47)	2.24 (2.16)	2.64 (2.49)	2.82 (2.42)	2.62 (2.34)	2.77 (2.48)			
Group							107	0.26	0.61
Time							162	1.34	0.27
Group X Time							162	0.14	0.87
Pain Interference	2.27 (2.75)	1.81 (2.15)	2.66 (2.77)	2.72 (2.79)	2.75 (2.69)	2.61 (2.42)			
Group							102	0.73	0.40
Time							163	1.00	0.37
Group X Time							163	1.69	0.19
Fatigue Frequency	5.37 (2.17)	5.17 (2.17)	5.27 (2.23)	5.69 (2.41)	5.00 (2.57)	4.64 (2.71)			
Group							108	0.16	0.69
Time							170	2.66	0.07
Group X Time							170	1.81	0.17
Fatigue Severity	4.25 (2.04)	3.84 (2.03)	4.28 (2.47)	4.47 (2.09)	3.81 (2.31)	3.63 (2.86)			
Group							109	0.01	0.92
Time							169	2.65	0.07
Group X Time							169	0.93	0.40
Fatigue Interference	3.22 (2.44)	2.53 (2.04)	2.87 (2.44)	3.65 (2.53)	3.42 (2.86)	3.20 (2.89)			
Group							106	1.36	0.25
Time							165	1.72	0.18
Group X Time							165	0.49	0.62
Breathlessness Frequency	1.73 (1.37)	1.75 (1.44)	1.71 (1.41)	1.73 (1.35)	1.86 (1.34)	1.98 (1.21)			
Group							107	0.30	0.58
Time							168	1.20	0.30
Group X Time							168	0.47	0.62
Breathlessness Severity	1.35 (1.00)	1.19 (0.95)	1.23 (0.97)	1.45 (1.09)	1.48 (1.09)	1.43 (0.82)			
Group							106	0.96	0.33

	TSM			**Education/support**					
	Baseline	**2 weeks post-intervention**	**6 weeks post-intervention**	**Baseline**	**2 weeks post-intervention**	**6 weeks post-intervention**			
Outcome **Fixed effect**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	***df***	***F***	***p***
Time							168	0.02	0.98
Group X Time							168	0.22	0.80
Breathlessness Distress	1.22 (1.12)	1.33 (1.35)	1.20 (1.23)	1.25 (1.19)	1.43 (1.37)	1.39 (1.22)			
Group							106	0.34	0.56
Time							167	1.74	0.18
Group X Time							167	0.23	0.80
Self-efficacy for Symptom Management	63.51 (16.80)	62.69 (17.41)	61.78 (19.59)	59.82 (17.33)	60.55 (19.75)	62.09 (20.87)			
Group							106	0.23	0.63
Time							167	0.08	0.92
Group X Time							167	0.85	0.43
Social Constraints	1.54 (0.69)	1.58 (0.82)	1.36 (0.56)	1.61 (0.71)	1.58 (0.68)	1.70 (0.92)			
Group							106	1.13	0.29
Time							170	0.28	0.76
Group X Time							170	2.35	0.10

Note. TSM = Telephone-delivered symptom management intervention; *SD* = standard deviation.

Table 5

Intent-to-Treat Results for Multilevel Linear Models Predicting Caregiver Outcomes ($n = 106$)

Outcome Fixed effect	TSM Baseline Mean (*SD*)	 2 weeks post-intervention Mean (*SD*)	 6 weeks post-intervention Mean (*SD*)	Education/support Baseline Mean (*SD*)	 2 weeks post-intervention Mean (*SD*)	 6 weeks post-intervention Mean (*SD*)	*df*	*F*	*p*
Self-efficacy for Managing the Patient’s Symptoms	60.01 (22.96)	52.89 (22.12)	59.16 (23.67)	58.22 (20.77)	58.48 (21.65)	56.79 (21.65)			
Group							104	0.20	0.66
Time							157	1.16	0.31
Group X Time							157	1.61	0.20
Self-efficacy for Managing Their Own Emotions	7.27 (1.82)	7.38 (1.92)	7.59 (1.66)	7.19 (1.64)	6.74 (2.01)	6.92 (2.18)			
Group							106	2.41	0.12
Time							161	0.73	0.48
Group X Time							161	3.21	0.04
Caregiving Burden: Impact on Schedule	13.69 (3.70)	13.74 (4.45)	13.89 (4.37)	14.64 (4.62)	13.89 (4.86)	14.10 (5.24)			
Group							107	0.62	0.43
Time							162	0.04	0.96
Group X Time							162	0.28	0.75
Caregiving Burden: Caregiver’s Esteem	32.10 (2.76)	32.49 (2.47)	32.54 (2.65)	32.04 (2.87)	32.13 (2.68)	32.31 (2.97)			
Group							103	0.20	0.65
Time							156	0.03	0.97
Group X Time							156	0.42	0.66
Caregiving Burden: Lack of Family Support	10.14 (4.58)	9.57 (4.67)	9.29 (5.17)	9.67 (4.38)	9.91 (4.94)	9.86 (4.78)			
Group							103	0.08	0.78
Time							156	0.39	0.68
Group X Time							156	0.14	0.87
Caregiving Burden: Impact on Health	7.82 (3.22)	8.23 (3.38)	8.11 (3.64)	8.04 (2.75)	7.93 (2.96)	8.17 (2.75)			

	TSM			**Education/support**					
	Baseline	**2 weeks post-intervention**	**6 weeks post-intervention**	**Baseline**	**2 weeks post-intervention**	**6 weeks post-intervention**			
Outcome **Fixed effect**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	***df***	***F***	***p***
Group							106	0.02	0.88
Time							162	1.24	0.29
Group X Time							162	0.32	0.73
Caregiving Burden: Impact on Finances	6.48 (2.71)	6.66 (3.16)	6.34 (2.72)	6.96 (3.07)	6.31 (2.96)	6.60 (3.22)			
Group							105	0.35	0.56
Time							161	0.02	0.98
Group X Time							161	1.02	0.36
Social Constraints	1.86 (0.85)	1.60 (0.71)	1.61 (0.80)	2.06 (0.79)	2.07 (0.92)	2.05 (0.90)			
Group							103	7.09	0.01
Time							160	0.39	0.68
Group X Time							160	2.65	0.07

Note. TSM = Telephone-delivered symptom management intervention; *SD* = standard deviation.