

*Original Article*

# 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 four 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.

**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 two- and six-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. *J Pain Symptom Manage* 2016;■:■-■. © 2016 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.

**Key Words**

*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.<sup>1</sup> Most lung cancer patients (85%) have regional or distant metastases at diagnosis, contributing to their high rate (80%) of multiple physical and psychological symptoms.<sup>2-4</sup> Lung cancer

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patients experience higher rates of anxiety and depressive symptoms and breathlessness than other cancer patients.<sup>5–7</sup> 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).<sup>2,8–11</sup> 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.<sup>12,13</sup>

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

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.<sup>26–28</sup> 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.<sup>29–31</sup> In addition, nonpharmacologic aspects of palliative care have a limited evidence base for use with lung cancer patients and caregivers.<sup>32–34</sup> To date, cognitive-behavioral interventions have reduced physical symptom severity in patients with various cancers and chronic illnesses<sup>35–41</sup> and reduced distress in primarily early-stage cancer patients and caregivers.<sup>32,38</sup> Two trials have tested emotion-focused interventions for couples coping with cancer and both showed improved relational outcomes.<sup>42,43</sup> 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 with usual care.<sup>44</sup> 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 and caregiver anxiety and self-efficacy for helping the patient manage symptoms.<sup>45</sup>

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. Although most previous symptom management trials with cancer patient-caregiver dyads have emphasized patient care,<sup>32,45–49</sup> TSM has a dual focus on patient and caregiver concerns. The intervention involves a blend of evidence-based cognitive-behavioral and emotion-focused strategies<sup>42,45,50–53</sup> 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 nonpharmacologic intervention and prevalent in this population.<sup>2,8–11,14,22</sup> The intervention was framed by Social Cognitive Theory, which hypothesizes that self-efficacy to implement symptom management strategies will result in improved health outcomes.<sup>54,55</sup> 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) compared with 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) compared with 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](http://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 cut-points for depressive symptoms (Patient Health Questionnaire-2 score  $\geq 3$  on this 0–6 scale)<sup>56</sup>;

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