Original Article

Acceptance and Commitment Therapy for Symptom Interference in Advanced Lung Cancer and Caregiver Distress: A Pilot Randomized Trial

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Abstract

Context. Advanced lung cancer patients typically have a poor prognosis and many symptoms that interfere with functioning, contributing to high rates of emotional distress in both patients and family caregivers. There remains a need for evidence-based interventions to improve functional outcomes and distress in this population.

Objectives. This pilot trial examined the feasibility and preliminary efficacy of telephone-based Acceptance and Commitment Therapy (ACT) for symptomatic, advanced lung cancer patients and their distressed family caregivers. Primary outcomes were patient symptom interference with functioning and patient and caregiver distress.

Methods. Symptomatic, advanced lung cancer patients and distressed caregivers ($n = 50$ dyads) were randomly assigned to six sessions of ACT or an education/support condition. Patients completed measures of symptom interference and measures assessing the severity of fatigue, pain, sleep disturbance, and breathlessness. Patients and caregivers completed measures of distress and illness acceptance and struggle.

Results. The eligibility screening rate (51%) and retention rate (76% at six weeks postintervention) demonstrated feasibility. No group differences were found with respect to patient and caregiver outcomes. Both groups showed a small, significant decrease in struggle with the illness over the study period, but did not show meaningful change in other outcomes.

Conclusion. Findings suggest that telephone-based ACT is feasible for many advanced lung cancer patients and caregivers, but may not substantially reduce symptom interference and distress. Low baseline levels of certain symptoms may have contributed to null findings. Next steps include applying ACT to specific, clinically meaningful symptom interference and varying intervention dose and modality. J Pain Symptom Manage 2019;58:632–644. © *2019 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.*

Key Words

Lung cancer, family caregivers, psychosocial intervention, symptom management, distress, Acceptance and Commitment Therapy

Introduction

Lung cancer is one of the most common cancers affecting men and women.[1] Most lung cancer patients are diagnosed with regional or distant stage disease,[1] resulting in various distressing symptoms.[2,3] The most prevalent symptoms in lung cancer patients include fatigue, sleep disturbance, pain, breathlessness, depressive symptoms, and anxiety.[2,4,5] These symptoms often co-occur and have been associated with impaired daily activities and quality of life (QoL).[6–8]

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Family caregivers also experience QoL impairment.[9–11] As many as 50% of family caregivers of lung cancer patients report clinically meaningful anxiety or depressive symptoms.[12–15] Caregiver distress may be related to the patient's poor prognosis, high symptom burden, and attributions of blame or stigma associated with the patient's tobacco use.[16–19] In addition, caregivers of lung cancer patients have reported challenges in performing caregiving tasks, such as monitoring symptoms.[17,20,21]

Growing evidence suggests that the early integration of standard oncologic and palliative care may improve QoL and possibly survival in advanced lung cancer patients and reduce caregiver distress.[22–24] Based on this evidence, clinical practice guidelines now emphasize this integration in lung cancer care.[25,26] However, nonpharmacologic aspects of palliative care for lung cancer patients and caregivers have mixed empirical support.[27–30] One pilot trial found that a telephone-based dyadic intervention for advanced lung cancer patients and caregivers reduced anxiety and depressive symptoms compared with usual care.[31] Another pilot trial compared a telephone-based dyadic intervention for symptomatic lung cancer patients of mixed stages and caregivers to an education/support condition.[32] Patient physical and psychological symptoms and caregiver psychological symptoms did not significantly change over time in either study condition. A third larger telephone-based trial for early-stage lung cancer patients and caregivers found that both caregiver-assisted coping skills training and education/support resulted in improved patient depression, lung cancer symptoms, and caregiver anxiety.[33] Thus, there remains a need to develop innovative interventions for advanced, symptomatic lung cancer patients and caregivers.

One intervention that shows promise for reducing symptom-related suffering in cancer is Acceptance and Commitment Therapy (ACT).[34,35] In contrast to traditional cognitive-behavioral therapy that aims to reduce symptoms and change maladaptive thoughts,[32,33] the goal of ACT is to increase psychological flexibility so that difficult thoughts, feelings, and symptoms interfere less with meaningful activities.[36] Psychological flexibility is defined as full awareness of the present moment while engaging in action consistent with deeply held values.[37] According to the ACT model, six psychological skills—mindfulness, perspective-taking, cognitive defusion, acceptance, value clarification, and committed action—facilitate psychological flexibility.[35,37]

ACT has a strong evidence base in chronic pain[38,39] and mental health[40] and has been tested in several pilot randomized controlled trials (RCTs) with cancer patients.[41–43] One RCT with late-stage ovarian cancer patients found that ACT produced large improvement in anxiety and depressive symptoms compared with cognitive-behavioral therapy.[42] Another pilot RCT with metastatic breast cancer patients found that ACT showed promise relative to an education/support condition with respect to fatigue interference with activities, mood, and cognition.[43] ACT has yet to be applied to cancer caregivers.

We developed an ACT intervention with the goal of reducing symptom interference (i.e., the degree to which symptoms interfere with activities, mood, and cognition) in advanced lung cancer patients and patient and caregiver distress. The intervention included the following components: mindfulness practices; acceptance of thoughts, feelings, and physical symptoms through metaphors and experiential exercises; clarification of personal values; and taking action steps consistent with these values. We tailored the intervention to the experiences of advanced lung cancer patients and caregivers and delivered it via phone to improve accessibility.

This pilot trial examined the feasibility and preliminary efficacy of ACT compared with an education/support condition that controlled for time and attention. We recruited advanced lung cancer patients who reported moderate-to-severe bother for at least one of six common symptoms (i.e., fatigue, sleep disturbance, pain, breathlessness, depressive symptoms, or anxiety) and their family caregivers with elevated distress. Feasibility was evaluated via recruitment, retention, and session completion rates. Preliminary efficacy was evaluated via ACT's effect on patient symptom interference (i.e., global symptom interference, fatigue interference, pain interference, and dyspnea task avoidance) and patient and caregiver distress relative to the education/support condition. Although symptom reduction is not the emphasis of ACT, this intervention has resulted in reduced symptoms in trials with medical populations, including cancer patients.[34,40] Thus, we compared the two interventions regarding the severity of patient fatigue, pain, sleep disturbance, and breathlessness. We also examined whether ACT improved patient and caregiver acceptance of the illness and reduced their sense of struggle with the illness.

Methods

Participants

Patient eligibility criteria were as follows: 1) a diagnosis of advanced lung cancer (i.e., Stage III or IV non-small cell or extensive stage small cell lung cancer) at least three weeks before enrollment; 2) moderate-to-severe bother for at least one symptom, defined as a Rotterdam Symptom item score ≥ 2 on a 1–4 scale for fatigue, pain, sleep disturbance, breathlessness, depressive symptoms, or worry[44]; and 3) a consenting primary family caregiver. Patients were ineligible if they 1) had severe cognitive impairment (i.e., three or more errors on a six-item cognitive screener),[45] 2) had a self-reported Eastern Cooperative Oncology Group score >2 (able to do little activity),[46,47] or 3) were receiving hospice care at the time of enrollment. Eligible caregivers lived with the patient or had visited the patient at least twice a week for the past month. In addition, eligible caregivers showed clinical or subclinical distress, defined as a T-score ≥55 on either the four-item Patient-Reported Outcomes Measurement Information System (PROMIS) anxiety or depression measure[48] or a Distress Thermometer score ≥3.[49] Both patients and caregivers had to be adults (≥18 years of age) who were fluent in English.

Procedures

Participants were recruited from the Indiana University (IU) Health Simon Cancer Center and other IU Health sites between October 2016 and November 2017. Study procedures were approved by the IU institutional review board. Initial patient eligibility was confirmed through chart review and consultation with the oncologist. Trained research assistants approached patients during an oncology clinic visit or through letters of invitation and telephone calls to describe the study. Interested patients identified their primary family caregiver and were screened for eligibility. If patients consented to participate, caregivers were approached in clinic or through telephone calls for eligibility screening and consent.

Participants completed individual baseline telephone assessments and were randomly assigned to either the ACT or education/support condition. Randomization was performed by a person who did not interact with participants using a SAS procedure and was stratified by patient gender and performance status (self-reported Eastern Cooperative Oncology Group scores 0 or 1 vs. 2).[46] Research assistants blind to study condition administered individual telephone assessments at two and six weeks postintervention, and each person received a $25 gift card per assessment.

Measures

Primary Outcomes. The primary outcome of patient symptom interference with functioning was assessed with the following measures: 1) six-item global symptom interference subscale of the MD Anderson Symptom Inventory,[50] 2) seven-item interference subscale of the Fatigue Symptom Inventory,[51] 3) four-item PROMIS scale for pain interference,[52] and 4) one PROMIS item assessing task avoidance related to dyspnea.[53,54] The primary outcome of patient and caregiver distress was assessed with the four-item PROMIS anxiety and depression measures[48] and the one-item Distress Thermometer.[49]

Secondary Outcomes. The following measures assessed the severity of patient physical symptoms: 1) the four-item PROMIS fatigue measure, 2) the four-item PROMIS sleep disturbance measure, and 3) the three-item PROMIS pain intensity measure.[53,54] In addition, patient breathlessness was evaluated with four items from the Memorial Symptom Assessment Scale.[55] Finally, patient and caregiver acceptance of the illness was measured with the PEACE questionnaire, which includes a seven-item Struggle with Illness subscale and a five-item Peaceful Acceptance subscale.[56]

Sociodemographics and Medical Variables. Patients and caregivers reported their demographic characteristics and mental health service use at baseline. Patient medical information was obtained via chart review.

General Aspects of Treatment Procedures and Therapist Training

Participants in both study conditions participated in six weekly 50-minute telephone sessions. Previous trials with advanced cancer patient-caregiver dyads support the feasibility of six sessions.[31,57] Patients and caregivers completed sessions 1 and 4–6 together via speakerphone, whereas sessions 2 and 3 were delivered to patients and caregivers separately. Holding both dyadic and individual sessions allowed the therapist to meet the shared and unique needs of patients and caregivers. All sessions were audiorecorded. The ACT condition was delivered by a master's level social worker with experience in ACT, whereas the education/support condition was delivered by a PhD student in clinical psychology with experience in psychoeducation. The therapists were trained and supervised on a weekly basis by two psychologists. Training included didactics and role-plays of treatment sessions detailed in manuals. Fidelity checklists were developed for both study conditions, and one of the psychologists randomly selected 18% of audio recordings to review for adherence to the manuals. The average fidelity rating was 96%. Both psychologists provided feedback on treatment adherence and quality.

Acceptance and Commitment Therapy

The ACT intervention targeted all processes of the ACT model of behavior change, including mindfulness, perspective taking, cognitive defusion, acceptance, values clarification, and committed action.[35,37] The intervention emphasized developing mindfulness skills and engaging in actions aligned with personal values. For example, many patients cope with symptoms by engaging in more rest and attempting to avoid symptom experiences—unfortunately, these well-intended coping strategies often lead patients to withdraw from valued activities. ACT supports patients' feasible engagement in these activities. In addition, patients and caregivers applied ACT skills to difficult thoughts and feelings. Each patient and caregiver was mailed handouts summarizing session topics and a CD that our team developed to guide mindfulness practices. Table 1 provides a summary of the intervention components.

During the first session, the therapist asked about the dyad's background, the patient's strategies for managing symptoms, and the caregiver's strategies for managing their own difficult thoughts and feelings. In addition, the concept of mindfulness was introduced. Across the six sessions, patients and caregivers practiced various mindfulness exercises, clarified their values, and set committed action steps aligned with their values. During each session, the therapist assessed participants' home practice of mindfulness and other skills and concluded with a discussion of practice for the upcoming week. Although each participant learned the same skills, in-session and home practices were tailored to their cancer or caregiving-related experiences and other challenges. For example, barriers to committed action steps were discussed. In addition, the mindfulness exercises did not focus on the breath, as breathing difficulties are associated with panic symptoms in many lung cancer patients.[58]

Education/Support Condition

Similar to other psychosocial intervention trials for cancer patient-caregiver dyads,[32,59] the comparison group was an education/support condition. The intervention involved supportive listening and directing patients and caregivers to resources for practical and health information and psychosocial support. Table 1 presents a summary of the education/support components. The sessions included an orientation to the medical center and treatment team, education regarding common QoL concerns experienced by patients and caregivers, and discussion of resources for psychosocial support, health information, and financial assistance. The therapist also provided tips for critically evaluating health information in books, magazines, and web sites. Each patient and caregiver was mailed handouts summarizing session topics and was asked to review them at home. Sessions were not tailored to participants, except for the omission of topics that did not apply to them. Although both study therapists engaged in supportive listening, specific intervention content did not overlap across study conditions.

Statistical Analyses

Descriptive statistics were computed to examine feasibility. The assumptions of normality and linearity were examined for each continuous variable. After applying a winsorization transformation to outliers on depressive symptoms, anxiety, and acceptance of illness variables, all skewness and kurtosis values were acceptable.[60] Baseline comparisons of study conditions were conducted for patients and caregivers separately using t-tests (or Fisher exact tests). Potential gender differences were evaluated. Linear mixed-model repeated-measures analyses in SPSS were used to examine the preliminary efficacy of ACT. These analyses are an intent-to-treat approach because they use all available data. Multilevel modeling for dyadic data, an approach that accounts for the nonindependence of data from members of the same dyad, was used for outcomes reported by patients and caregivers.[61,62] Models included the main effects of study group, time, and role (patient or caregiver) and all interaction effects (e.g., group × time, group × time × role). Both study group and time were categorical variables

Table 1
Summary of Topics Covered in Each Intervention Condition

Acceptance and Commitment Therapy	Education/Support
• Discuss patient and caregiver coping strategies for managing symptoms and distress, including control vs. non-control-based strategies • Experiential practice of mindfulness during sessions and at home (e.g., notice an object/scene, use the metaphor of leaves on a stream to notice changing thoughts and feelings) • Practice cognitive defusion—noticing thoughts rather than being caught up in thoughts (e.g., passengers on the bus metaphor) • Cultivate perspective-taking or a locus from which to observe and accept changing experiences (e.g., imagine feelings about a stressful situation as a physical object) • Identify personal values (e.g., being a loving partner, engaging in spiritual practices) • Plan and practice values-consistent actions, despite symptoms or distress	• Orient to the medical center and treatment team, provide overview of quality of life issues, and discuss physical quality of life • Discuss social quality of life (e.g., family challenges related to cancer, employment) and refer to resources • Discuss other aspects of quality of life (e.g., changes in roles and activities, emotional and cognitive functioning) and refer to resources • Discuss financial challenges and resources for managing them • Describe and practice methods for evaluating health information in books, magazines, and web sites • Review previous sessions and refer to web sites with cancer-related information

in these models to focus the analyses on mean differences across groups and time. Treatment effects are evidenced by a significant interaction between study group and time. A significant group × time × role interaction indicates that the treatment effects differ between patients and caregivers. For outcomes that only patients or caregivers reported, models included the main effects of study group and time and the group × time interaction. For each analysis, the partial correlation coefficient (*pr*), an effect size statistic, was computed using the *F* value and degrees of freedom.[63] Two-sided P-values < 0.05 were considered statistically significant.

At baseline, seven patient outcomes, but none of the caregiver outcomes, varied by gender (data not shown). When patient gender was included in the multilevel models as a potential moderator of treatment effects, none of the moderation findings were significant (data not shown).

Results

Feasibility

Of the 331 advanced lung cancer patients who were approached, 134 declined to participate, 51 were ineligible, 60 could not be reached via phone, and 86 consented (Fig. 1). Patients agreeing to the eligibility screening did not differ from refusers with respect to race or age (P's > 0.05). However, male patients were more likely than female patients to agree to screening, $\chi^2(1, N = 239) = 4.43$, $P < 0.05$. Of the 86 caregivers who were approached, three declined participation, 24 were ineligible, and four could not be reached via phone. Thus, 55 dyads were eligible and consented to participate. Primary reasons for refusal were lack of interest, time constraints, and health. Five dyads withdrew before randomization because of lack of interest, medical reasons, or loss to follow-up. Twenty-five of the remaining 50 dyads

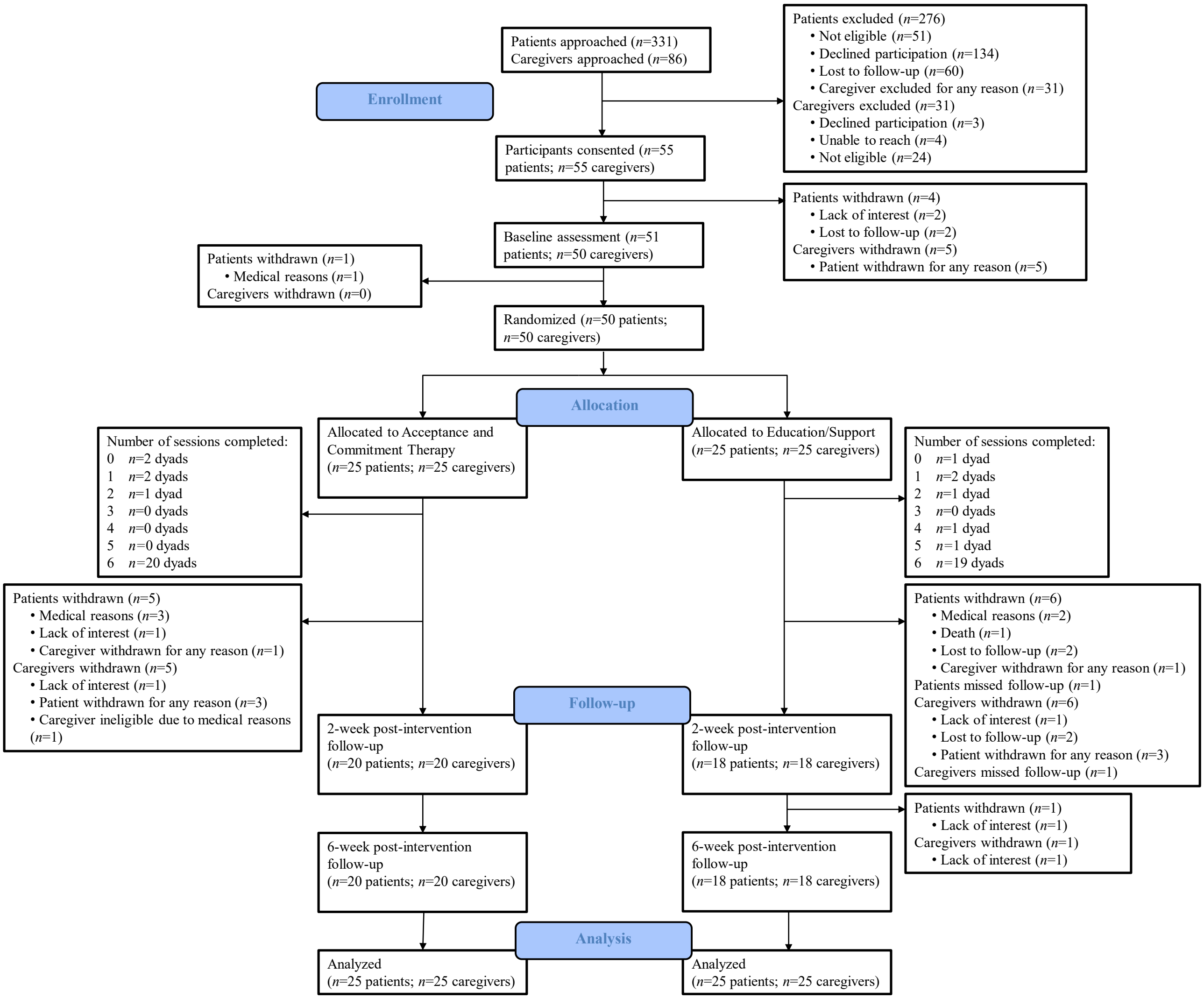

Fig. 1. Study CONSORT diagram.

Table 2
Patient and Caregiver Characteristics and Group Comparisons at Baseline

	Patients ($n = 50$)			Caregivers ($n = 50$)		
Characteristics	ACT ($n = 25$)	Education/Support ($n = 25$)	*t*-Test/Fisher Exact Test, *P*	ACT ($n = 25$)	Education/Support ($n = 25$)	*t*-Test/Fisher Exact Test, *P*
Sex, *n* (%)			1.00			0.73
Male	14 (56.00)	14 (56.00)		6 (24.00)	4 (16.00)	
Female	11 (44.00)	11 (44.00)		19 (76.00)	21 (84.00)	
Age			0.73			0.04
Mean	63.20	62.00		61.64	52.40	
SD	11.27	13.13		11.52	18.10	
Range	35–81	37–82		36–83	22–78	
Race, *n* (%)			0.42			0.70
Non-Hispanic White	20 (80.00)	23 (92.00)		20 (80.00)	22 (88.00)	
Employment status, *n* (%)			0.57			0.73
Employed full or part-time	4 (16.00)	7 (28.00)		12 (48.00)	15 (60.00)	
Retired	14 (56.00)	11 (44.00)		10 (40.00)	7 (28.00)	
Unemployed	7 (28.00)	6 (24.00)		3 (12.00)	3 (12.00)	
Missing	0 (0)	1 (4.00)		0 (0)	0 (0)	
Household income, *n* (%)			0.57			0.66
$0–$50,999	10 (40.00)	8 (32.00)		10 (40.00)	8 (32.00)	
$51,000–$99,999	6 (24.00)	10 (40.00)		7 (28.00)	8 (32.00)	
$100,000 or more	6 (24.00)	6 (24.00)		5 (20.00)	8 (32.00)	
Missing	3 (12.00)	1 (4.00)		3 (12.00)	1 (4.00)	
Years of education			0.33			0.56
Mean	14.28	13.56		14.44	14.88	
SD	2.57	2.65		2.57	2.71	
Range	12–20	7–18		11–19	10–21	
Caregiver relationship to the patient, *n* (%)						0.75
Spouse/partner	—	—		19 (76.00)	17 (68.00)	
Other family member	—	—		6 (24.00)	8 (32.00)	
Caregiver lives with the patient, *n* (%)	—	—		20 (80.00)	19 (76.00)	1.00
Married/living with a partner, *n* (%)	20 (80.00)	18 (72.00)	0.74	21 (84.00)	20 (80.00)	1.00
Psychiatric medication, *n* (%)[a]	9 (36.00)	13 (52.00)	0.39	11 (44.00)	10 (40.00)	1.00
Psychotherapy/counseling, *n* (%)[a]	3 (12.00)	0 (0)	0.24	1 (4.00)	1 (4.00)	1.00
Study site, *n* (%)			1.00			
Indiana University Simon Cancer Center	23 (92.00)	22 (88.00)		—	—	
Other Indiana University Health Sites	2 (8.00)	3 (12.00)		—	—	
Disease stage, *n* (%)			0.54			
NSCLC Stage III	5 (20.00)	9 (36.00)		—	—	
NSCLC Stage IV	19 (76.00)	15 (60.00)		—	—	
SCLC Extensive Stage	1 (4.00)	1 (4.00)		—	—	
Time since diagnosis, yrs			0.49			
Mean	1.79	1.41		—	—	
SD	2.03	1.77		—	—	
Range	0.14–8.30	0.17–7.71		—	—	

(*Continued*)

Table 2
Continued

Characteristics	Patients ($n = 50$)		t-Test/Fisher Exact Test, P	Caregivers ($n = 50$)		t-Test/Fisher Exact Test, P
	ACT ($n = 25$)	Education/Support ($n = 25$)		ACT ($n = 25$)	Education/Support ($n = 25$)	
Treatments received, n (%)						
Chemotherapy	16 (64.00)	15 (60.00)	1.00	—	—	
Radiation	10 (40.00)	8 (32.00)	0.77	—	—	
Chemoradiation	6 (24.00)	9 (36.00)	0.54	—	—	
Surgery to remove primary tumor	4 (16.00)	8 (32.00)	0.32	—	—	
Surgery to remove metastases	1 (4.00)	2 (8.00)	1.00	—	—	
Smoking, n (%)			0.57			0.56
Never smoked	7 (28.00)	5 (20.00)		14 (56.00)	12 (48.00)	
Current smoker	13 (52.00)	17 (68.00)		7 (28.00)	5 (20.00)	
Former smoker	5 (20.00)	3 (12.00)		4 (16.00)	7 (28.00)	
Patient ECOG score[b]			0.83			
Mean	0.96	1.00		—	—	
SD	0.69	0.66		—	—	
Range	0.00−2.00	0.00−2.00		—	—	
Symptom bother[c]						
Depressed mood, n (%)	10 (40.00)	10 (40.00)	1.00	—	—	
Worrying, n (%)	15 (60.00)	15 (60.00)	1.00	—	—	
Pain, n (%)	15 (60.00)	17 (68.00)	0.77	—	—	
Difficulty sleeping, n (%)	13 (52.00)	15 (60.00)	0.78	—	—	
Shortness of breath, n (%)	15 (60.00)	13 (52.00)	0.78	—	—	
Tiredness, n (%)	20 (80.00)	23 (92.00)	0.42	—	—	
Number of symptoms[d]			0.63	—	—	
Mean	3.52	3.72		—	—	
SD	1.36	1.57		—	—	
Range	2.00−6.00	1.00−6.00		—	—	
Depressive symptoms, n (%)[e]	—	—		13 (52.00)	11 (44.00)	0.78
Anxiety, n (%)[e]	—	—		18 (72.00)	20 (80.00)	0.74
General distress, n (%)[f]	—	—		22 (88.00)	23 (92.00)	1.00

ACT = Acceptance and Commitment Therapy; NSCLC = non−small cell lung cancer; SCLC = small cell lung cancer; ECOG = Eastern Cooperative Oncology Group; PROMIS = Patient-Reported Outcomes Measurement Information System.

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

[b] Assessed at screening.

[c] Score of 2 or higher (moderate-to-severe symptom bother) on Rotterdam Symptom Checklist items at screening.

[d] Number of Rotterdam Symptom Checklist items with scores of 2 or higher (moderate-to-severe symptom bother) at screening.

[e] T-score of 55 (one-half SD above the population mean) or higher on four-item PROMIS measure at screening.

[f] Distress Thermometer score of 3 or higher indicating clinical or subclinical distress at screening.

Table 3

Intent-to-Treat Results for Multilevel Linear Models Predicting Outcomes ($N = 50$ Dyads)

	ACT			Education/Support						
	Baseline	Two Weeks Postintervention	Six Weeks Postintervention	Baseline	Two Weeks Postintervention	Six Weeks Postintervention				
Outcome Fixed Effect	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	df	*F*	*P*	*pr*
Primary Outcomes										
Patient global symptom interference	3.07 (0.56)	2.96 (0.59)	2.98 (0.59)	2.81 (0.56)	3.39 (0.62)	3.47 (0.61)				
Group							45	0.09	0.76	0.05
Time							73	0.38	0.69	0.07
Group × time							73	0.68	0.51	0.10
Patient fatigue interference	2.65 (0.50)	2.73 (0.53)	2.83 (0.53)	2.60 (0.50)	2.79 (0.55)	2.76 (0.54)				
Group							49	0.00	0.98	0.00
Time							77	0.18	0.83	0.05
Group × time							77	0.03	0.97	0.02
Patient pain interference	9.12 (0.94)	8.46 (1.00)	8.21 (1.00)	8.12 (0.94)	7.45 (1.03)	7.66 (1.03)				
Group							48	0.50	0.48	0.10
Time							78	0.83	0.44	0.10
Group × time							78	0.09	0.92	0.03
Patient dyspnea task avoidance	1.08 (0.21)	1.09 (0.23)	0.99 (0.23)	0.80 (0.21)	0.52 (0.24)	0.61 (0.24)				
Group							46	2.47	0.12	0.22
Time							77	0.55	0.58	0.08
Group × time							77	0.45	0.64	0.08
Patient depressive symptoms	6.08 (0.65)	6.15 (0.67)	5.92 (0.67)	7.18 (0.65)	6.89 (0.68)	7.05 (0.68)				
Caregiver depressive symptoms	6.64 (0.58)	5.80 (0.62)	5.95 (0.62)	7.20 (0.58)	6.20 (0.65)	6.34 (0.65)				
Group							48	1.03	0.31	0.15
Time							78	2.59	0.08	0.18
Role							43	0.26	0.61	0.08
Time × role							81	1.23	0.30	0.12
Group × time							78	0.15	0.86	0.04
Group × role							43	0.53	0.47	0.11
Group × time × role							81	0.06	0.94	0.03
Patient anxiety symptoms	6.36 (0.72)	6.26 (0.74)	5.95 (0.74)	7.69 (0.72)	7.54 (0.76)	7.24 (0.76)				
Caregiver anxiety symptoms	7.60 (0.65)	7.23 (0.69)	6.92 (0.69)	8.16 (0.65)	7.68 (0.72)	7.29 (0.72)				
Group							47	1.34	0.25	0.17
Time							76	2.48	0.09	0.18
Role							48	1.83	0.18	0.19
Time × role							81	0.21	0.81	0.05
Group × time							76	0.02	0.98	0.02
Group × role							48	0.79	0.38	0.13
Group × time × role							81	0.01	0.99	0.01
Patient general distress	2.64 (0.50)	2.97 (0.53)	2.62 (0.53)	3.20 (0.50)	2.40 (0.55)	3.43 (0.54)				
Caregiver general distress	4.12 (0.46)	3.83 (0.50)	3.43 (0.50)	4.12 (0.46)	5.06 (0.52)	3.71 (0.52)				
Group							46	0.52	0.47	0.11
Time							76	0.66	0.52	0.09
Role							42	18.41	0.00	0.55

(*Continued*)

Table 3
Continued

	ACT			Education/Support						
	Baseline	Two Weeks Postintervention	Six Weeks Postintervention	Baseline	Two Weeks Postintervention	Six Weeks Postintervention				
Outcome Fixed Effect	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	df	*F*	*P*	*pr*
Time × role							80	2.87	0.06	0.19
Group × time							76	0.16	0.85	0.05
Group × role							42	0.19	0.67	0.07
Group × time × role							80	3.68	0.03	0.21
Secondary Outcomes										
Patient fatigue	10.56 (0.83)	10.83 (0.89)	10.38 (0.89)	10.04 (0.83)	9.99 (0.92)	10.43 (0.92)				
Group							51	0.17	0.68	0.06
Time							82	0.03	0.98	0.02
Group × time							82	0.30	0.74	0.06
Patient pain intensity	6.64 (0.55)	6.46 (0.58)	6.31 (0.58)	6.36 (0.55)	6.22 (0.59)	6.32 (0.59)				
Group							49	0.05	0.82	0.03
Time							78	0.22	0.80	0.05
Group × time							78	0.14	0.87	0.04
Patient sleep disturbance	10.56 (0.71)	10.24 (0.78)	10.04 (0.78)	11.24 (0.71)	10.15 (0.81)	9.85 (0.81)				
Group							44	0.02	0.88	0.02
Time							74	1.64	0.20	0.15
Group × time							74	0.38	0.69	0.07
Patient breathlessness	1.08 (0.19)	1.16 (0.21)	1.19 (0.21)	1.05 (0.19)	0.84 (0.22)	0.69 (0.22)				
Group							49	1.40	0.24	0.17
Time							80	0.37	0.69	0.07
Group × time							80	1.32	0.27	0.13
Patient struggle with illness	12.24 (0.97)	11.81 (0.99)	11.26 (0.99)	13.00 (0.97)	12.67 (1.01)	12.30 (1.01)				
Caregiver struggle with illness	13.64 (0.77)	11.95 (0.80)	12.10 (0.80)	13.80 (0.77)	13.74 (0.82)	13.12 (0.82)				
Group							49	0.80	0.38	0.13
Time							77	5.68	0.01	0.26
Role							50	2.15	0.15	0.20
Time × role							79	0.58	0.56	0.09
Group × time							77	1.12	0.33	0.12
Group × role							50	0.01	0.93	0.01
Group × time × role							79	1.40	0.25	0.13
Patient illness acceptance	17.28 (0.60)	17.30 (0.62)	17.75 (0.62)	16.60 (0.60)	16.15 (0.64)	16.03 (0.63)				
Caregiver illness acceptance	15.64 (0.67)	15.96 (0.70)	16.31 (0.70)	14.68 (0.67)	14.90 (0.71)	15.67 (0.71)				
Group							51	1.96	0.17	0.19
Time							78	2.34	0.10	0.17
Role							49	8.15	0.01	0.38
Time × role							77	2.69	0.07	0.18
Group × time							78	0.44	0.64	0.08
Group × role							49	0.10	0.75	0.05
Group × time × role							77	1.70	0.19	0.15

ACT = Acceptance and Commitment Therapy; Mean = Estimated marginal means; *pr* = partial correlation.

were randomized to the ACT intervention, and 25 were randomized to the education/support intervention. Most dyads (39 of 50, 78%) completed all six sessions and were retained at six-week follow-up (38 of 50, 76%).

Participant Characteristics

Table 2 presents participant characteristics by study group and group comparisons at baseline. The majority of patients (56%) were men and most caregivers (80%) were women. Patients and caregivers were primarily white and had an average of 14 years of education. A range of income levels were represented. Most caregivers (72%) were spouses or partners of the patient. Demographics, medical factors, and outcome variables did not vary by study condition at baseline, with the exception of caregiver age.

Preliminary Efficacy

Primary Outcomes. Results of the mixed-effects model analyses showed no group × time effects on indicators of patient symptom interference (i.e., global symptom interference, fatigue interference, pain interference, and dyspnea task avoidance; Table 3). Effect sizes for these group × time effects were small (prs = 0.02–0.10). In addition, mixed-model analyses showed no group × time effects for patient or caregiver depressive symptoms, anxiety, and general distress (prs = 0.02–0.05). There were also no significant main effects of time, suggesting that primary outcome variables did not change on average during the study period. Although there was a significant group × time × role interaction for general distress (pr = 0.21), mean changes in general distress from baseline were small at both follow-ups, irrespective of study group and role.

Secondary Outcomes. Mixed model analyses showed no group × time effects on patient physical symptom severity (i.e., fatigue, pain, sleep disturbance, and breathlessness; Table 3), with effect sizes in the small range (prs = 0.04–0.13). In addition, there were no group × time effects on patient and caregiver struggle with illness and illness acceptance (prs = 0.12 and 0.08, respectively; Table 3). However, there was a significant main effect of time on struggle with illness (pr = 0.26), indicating that participants in both groups, on average, reported a small decrease in struggle with illness over the study period. In addition, there was a significant main effect of role on illness acceptance, such that patients, on average, had higher levels than caregivers (pr = 0.38).

Discussion

This trial is the first to examine ACT for cancer patient-caregiver dyads and the first to test ACT for those coping with lung cancer. The strong recruitment rate (51%) and retention at six weeks postintervention (76%) support intervention feasibility. Researchers have documented challenges in recruiting and retaining lung cancer patients, given their high symptom burden.[64] Our recruitment and retention rates were comparable with those of couple-based intervention trials in cancer, most of which targeted dyads coping with nonmetastatic disease.[27]

Preliminary evidence of ACT's efficacy was not obtained. Compared with the education/support condition, ACT did not lead to reduced patient symptom interference with functioning or reduced patient or caregiver distress. In addition, compared with education/support, ACT did not reduce the severity of patient fatigue, pain, sleep disturbance, or breathlessness. ACT also did not improve patient and caregiver illness acceptance, and struggle. Both groups reported a small, significant decrease in struggle with the illness over the study period, but did not show meaningful change in other study outcomes.

Our findings are partially consistent with those of previous intervention trials for cancer dyads. Indeed, two other telephone-based psychosocial intervention trials with lung cancer dyads found no treatment effect relative to an education/support condition.[32,33] However, comparisons across trials with lung cancer dyads should be made with caution, given differences in eligibility criteria (e.g., cancer stage, symptoms), intervention dose (range = 4–14 sessions), and format (e.g., focus on patient vs. dyad).[31–33] The comparison group might also affect results, as evidenced by previous large effects of a telephone intervention on advanced lung cancer dyads' distress compared with usual care.[31]

Several factors might account for the current findings. First, participants reported relatively good functioning at baseline. Thus, most outcomes had, on average, moderate room for improvement over the study period, which may have limited our ability to detect intervention effects. In addition, similar to the general population of lung cancer patients,[65] many participants in our trial had low incomes. Stressors related to socioeconomic disadvantage may have been a greater focus for some participants than the intervention sessions' content. However, neither study group showed worsening symptom and distress outcomes over time. Because we did not include a usual care condition, we do not know if this group would have shown worsening outcomes over time relative to ACT and education/support.

Finally, the brevity of the intervention and telephone delivery might have reduced intervention effects. To date, meta-analyses of psychosocial interventions for cancer caregivers and cancer patient-caregiver dyads have found mixed evidence of associations between intervention dose and study outcomes.[27,29] The current number of sessions is similar to most couple-based interventions in cancer.[27] There is also no evidence that the phone modality is inferior to in-person treatment, but these modalities have rarely been compared.[29]

Several potential directions for future research may build on the growing ACT literature in cancer and other chronic illnesses. First, researchers should consider enrolling patients with a specific symptom that interferes with functioning and targeting this interference in ACT. Applying ACT skills to a specific, clinically meaningful problem may maximize intervention efficacy. Second, research is needed to elucidate mechanisms underlying beneficial effects of ACT on health outcomes found in previous trials.[34,40] For example, if mindfulness or value-based action is driving the health effects of ACT, then these components could be emphasized in future trials. Finally, although this trial included both dyadic and individual sessions, future research may directly compare these approaches.

Limitations of the study warrant mention. The sample was primarily White and recruited from medical centers in Indiana, thereby limiting the generalizability of the findings. In addition, patients with moderate symptom bother and caregivers with subclinical distress were eligible, which may have led to smaller intervention effects. It is unclear whether male patients' higher rates of eligibility screening compared with female patients affected trial results. Finally, the sample size reduced statistical power. However, the goal of this pilot study was to determine intervention feasibility and generate estimates of effects for a larger, fully-powered trial.

This trial and other pilot ACT trials[41–43] support ACT's feasibility for many cancer patients and caregivers. Larger trials are needed before drawing conclusions regarding ACT's impact on functioning and distress in this population and moderators of its effects. These trials could also assess ACT's impact on value-based action, social outcomes, and clinical decisions and the potential benefits of increasing the intervention dose. Subsequently, implementation studies could examine flexible treatment delivery methods. Given the high symptom burden associated with advanced lung cancer,[2,3,18,19] testing novel psychosocial interventions for these patients and caregivers should be a high priority for future research.

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