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Delivering Problem-Solving Therapy to Family Caregivers of People with Cancer: A Feasibility Study in Outpatient Palliative Care

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Abstract

Objective: In response to the well-documented need for evidence-based cancer caregiver support, we examined the feasibility of problem-solving therapy for family caregivers of cancer patients receiving outpatient palliative care and investigated the impact of problem-solving therapy on family caregivers' anxiety, depression, and quality of life.

Methods: We conducted a feasibility study of a structured problem-solving therapy intervention delivered to family caregivers of cancer patients receiving outpatient palliative care from an academic health center in the Midwestern United States. Participants ($N = 83$) were randomly assigned to receive usual care or usual care plus a problem-solving therapy intervention, which was delivered over three sessions via web-based videoconferencing or telephone. Descriptive statistics were used to determine feasibility relative to recruitment, retention, and fidelity to core intervention components. Outcome data were analyzed using ordinary least squares multiple regression.

Results: Problem-solving therapy for family caregivers of patients with cancer was found to be highly feasible in the outpatient palliative care setting. Caregivers who received problem-solving therapy reported less anxiety than those who received only usual care ($p = .03$). No statistically significant differences were observed for caregiver depression ($p = .07$) or quality of life ($p = .06$).

Conclusions: Problem-solving therapy is a feasible and promising approach to reducing cancer family caregivers' anxiety in the outpatient palliative care setting. Further testing in multiple sites is recommended.

Keywords

anxiety; cancer; caregivers; depression; family; oncology; problem solving; quality of life

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Conflict of Interest Statement

All authors declare no conflict of interest.

1. Background

In recent decades, the primary setting for cancer care has shifted from the hospital inpatient unit to the outpatient clinic, leaving family caregivers (FCGs) responsible for providing the majority of patient care in the home, often with little support or preparation.^{1,2} The numerous stressors associated with family caregiving for cancer patients are well documented and include insufficient or problematic communication with healthcare providers, lack of skill needed to complete specific tasks (e.g., administering medications, changing dressings), social isolation, and unavailability of necessary information.³ These stressors can lead to anxiety, depression, fatigue, neglect of self-care and, for particularly strained caregivers, psychological symptoms that mirror those experienced by trauma survivors.^{3,4} Early studies involving biomarkers have also identified a physiological toll associated with cancer caregiving stress, suggesting that highly stressed FCGs may be at increased risk for morbidity and mortality from certain diseases.⁵ The extant literature is clear: Cancer caregiving often takes place in a highly stressful emotional and social context, leaving FCGs vulnerable to significant, potentially long-lasting, adverse effects.

1.1 Family Caregiver Support in Palliative Oncology Care

Palliative oncology, defined as “the integration into cancer care of therapies to address the multiple issues that cause suffering for patients and their families and impact their quality of life,”⁶ explicitly espouses a commitment to supporting FCGs.^{7–10} Although commonly misunderstood to be limited to end-of-life care, in the United States palliative oncology is an interdisciplinary service available to patients and families across the full cancer trajectory. Research documenting the multiple benefits of early palliative care¹¹ has led the American Society of Clinical Oncology (ASCO) to recommend that many patients and families be offered palliative services concurrent with standard oncologic care as early as the time of initial diagnosis,¹² as palliative care can be provided either alongside interventions with a curative intent or as an alternative to disease-directed therapies. Although most palliative oncology in the United States is presently provided on an inpatient basis, it is increasingly being offered in outpatient clinics,¹³ creating a potentially ideal opportunity to provide additional support to FCGs in an effort to decrease their distress and improve their quality of life. However, palliative oncology teams wishing to capitalize on this opportunity are limited by the paucity of evidence-based interventions to support FCGs in general¹⁴ and in the outpatient palliative care setting in particular.

1.2 Problem-Solving Therapy for Family Caregivers

Problem-solving therapy (PST) is a psychosocial intervention that aims to enhance coping effectiveness for individuals facing stressors ranging from daily hassles to major traumatic events.¹⁵ The theoretical framework underpinning PST is the relational/problem-solving model of stress,¹⁶ which conceptualizes psychological distress such as anxiety and depression as the consequence of ineffective coping. The model suggests that, by enhancing problem-solving ability, PST can minimize the negative effects of stressful life events, leading to improved well-being (i.e., decreased anxiety and depression and greater quality of life).

While prior studies have identified PST as a promising strategy to reduce distress and improve the quality of life of individuals experiencing stressors associated with cancer caregiving,^{17–20} its feasibility and efficacy as a stand-alone intervention in outpatient palliative oncology settings remains unknown. Thus, in preparation for a large multisite trial, our research team sought to test the feasibility of a PST intervention for FCGs in the ambulatory palliative care setting. Specifically, we set out to achieve the following aims: (1) to examine the feasibility of PST for FCGs of cancer patients receiving outpatient palliative care relative to recruitment, retention, and fidelity to core intervention components; and (2) to investigate the impact of PST on FCGs' anxiety, depression, and quality of life. Our corresponding hypotheses were (1) that PST could be feasibility delivered to FCGs of cancer patients receiving outpatient palliative care and (2) that it would result in decreased caregiver anxiety and depression and improved quality of life.

2. Methods

To achieve the aforementioned aims, we conducted a single-site randomized clinical trial of a structured PST intervention for FCGs of people with cancer receiving outpatient palliative care. The University of Missouri Health Sciences Institutional Review Board (IRB) reviewed and approved all study activities (Project #2002215). The study was registered at clinicaltrials.gov (Identifier: NCT02427490).

2.1 Participant Recruitment

After securing IRB approval, we recruited study participants from the ambulatory palliative care clinic of an academic health center in the Midwestern United States from October 2015 to February 2017. Clinicians provided an informational brochure to FCGs accompanying patients with cancer to the palliative care clinic and requested permission to share their contact information with the research team. In addition, we placed study brochures in high-traffic clinical areas (e.g., oncology waiting rooms, patient and family resource centers).

The study research nurse reached out to interested FCGs via telephone or email to assess their eligibility and schedule a face-to-face informational meeting at the clinic, the FCG's home, or another agreed upon location. During the informational meeting, FCGs read, discussed, and – if willing to participate – signed an informed consent document, retaining a copy for their personal records. Inclusion criteria required that participants were English-speaking adult family caregivers of adult patients diagnosed with cancer who were receiving palliative care. Family caregivers included those individuals who provided significant, unpaid care to a person living with cancer; a biological or legal relationship was not required. In addition, participants were required to have sufficient hearing (either naturally or with assistive devices) to allow their participation in a technologically-mediated intervention. Individuals not receiving formal services from the specialty palliative care clinic were deemed eligible for participation if the patient for whom they provided care was receiving treatment with a palliative intent from the primary oncology team, as understood by the FCG. Multiple FCGs per patient were allowed to enroll in the study. After the FCG signed the informed consent document, the research nurse opened a numbered sealed envelope, prepared in advance, revealing whether the FCG had been randomly assigned to

receive usual care (Group 1) or usual care in addition to PST (Group 2). A CONSORT flow diagram²¹ summarizing participant recruitment and randomization is provided in Figure 1 (all participants were analyzed in their randomized groups regardless of their duration in the study).

2.2 Study Arms

2.2.1. Group 1: Usual care.—FCGs randomized to Group 1 experienced no changes in the care they or their patient received due to their participation in the research study. For these individuals, usual care continued according to each patient and family’s individualized treatment plan based on previously established goals of care. While the specific constellation of services provided as part of usual care varied, services available to all FCGs participating in the study included routine education and ongoing support related to pain and symptom management, professionally-facilitated support groups, and oncology social work services which, in this specific setting, tended to focus primarily on resource allocation versus delivery of formalized psychosocial support.

2.2.2. Group 2: Usual care plus PST.—FCGs randomized to Group 2 received usual care in addition to PST. The PST intervention we tested was adapted with permission from Demiris et al.’s¹⁸ Problem-Solving Intervention to Support Caregivers in End-of-Life Settings (or “PISCES”). Modifications included revised intervention materials that featured cancer-specific examples, referenced palliative care providers, and illustrated the application of problem-solving techniques across the disease and caregiving trajectory.

A trained research nurse delivered the PST intervention to FCGs over three separate sessions, spaced approximately one week apart. FCGs were given the option of receiving the intervention by telephone, over web-based videoconferencing, or any combination of the two. All sessions were digitally audio-recorded to permit monitoring of treatment fidelity. The first session focused on topics such as visualizing success, positive self-talk, and using emotions adaptively. During the second session, FCGs selected a specific caregiving problem and brainstormed possible solutions. In the third and final session, FCGs weighed the pros and cons of various possible solutions to their selected problem, identified a solution (or combination of solutions) they judged to be feasible and likely to result in the most desirable outcome(s), and developed a detailed plan for its implementation. Through this process, FCGs had the opportunity to learn broadly applicable problem-solving techniques and to apply them to an acute caregiving stressor.

2.3 Study Measures

2.3.1 Feasibility measures.—To measure progress toward recruiting and retaining an adequately large study sample, we established monthly recruitment and retention goals (established by *a priori* power analysis, described in Section 2.4.1) and noted our progress toward achieving them in a shared study database. To measure the degree of fidelity to core intervention components, the study Principal Investigator (PI) or designee reviewed a randomly selected sample of 25% of the audio-recorded intervention sessions and evaluated them using a treatment fidelity assessment form developed specifically for the study. Fidelity

scores for each session ranged from 0 to 100%, with a score of 100% reflecting complete fidelity to the intervention protocol.

2.3.2 Caregiver outcome measures.—In addition to reporting basic demographic information, FCGs participating in the study completed standardized instruments measuring their anxiety, depression, and quality of life. The Generalized Anxiety Disorder 7-item scale (GAD-7)²² measured the frequency with which FCGs experienced symptoms of anxiety such as excessive restlessness, uncontrollable worrying, and irritability. GAD-7 total scores range from 0 to 21; higher scores reflect greater anxiety. The GAD-7's internal consistency (Chronbach's alpha = 0.92) and test-retest reliability have been supported by prior research.²² The Patient Health Questionnaire 9-item scale (PHQ-9)²³ measured the frequency with which respondents experienced symptoms of depression such as anhedonia, sleep disturbance, and impaired concentration. PHQ-9 total scores range from 0 to 27; higher scores reflect greater depression. The PHQ-9's internal consistency (Cronbach's alpha = 0.89) and test-retest reliability have been supported by prior research.²³ The Caregiver Quality of Life Index – Revised (CQLI-R)²⁴ measured FCGs' quality of life in four domains: emotional, social, financial, and physical. Total CQLI-R scores range from 0 to 40; higher scores indicate better quality of life. The CQLI-R's internal consistency (Chronbach's alpha = 0.769) and test-retest reliability have been supported by prior research.²⁴

FCGs in both study groups completed the GAD-7, PHQ-9, and CQLI-R according to the same administration schedule, which included the following approximate time points: T₀ (baseline/study enrollment), T₁ (day 15/intervention midpoint for Group 2), T₂ (day 30/intervention conclusion for Group 2), and T₃ (day 60/study exit). With the exception of baseline measures, which were completed on paper during their enrollment visit, FCGs were given the option of completing the instruments online via Qualtrics (Provo, UT) or by providing their responses verbally by telephone.

2.4 Data Analysis

2.4.1 Statistical power calculation.—We based our *a priori* power calculation on changes in GAD-7²² total scores, as the instrument measures a key variable of interest (anxiety) and has demonstrated responsiveness to caregiver PST intervention in previous research.¹⁸ Our sample size calculation was based on a one-tailed test of significance and the following assumptions: 1) the difference in GAD-7 total score means between the usual care and intervention groups would be 2 points, the documented clinically significant effect;^{25,26} 2) the variance of scores would total 4.93;²⁷ 3) appropriate error protection would be as follows: $\alpha = .20$, $\beta = .20$; and 4) participant attrition would equal 14%, half of patient attrition reported in a recent meta-analysis of palliative oncology trials,²⁸ reflecting an assumption that FCGs would be able to actively participate in research longer than seriously ill patients. Taking these factors into consideration, we concluded that a sample of 41 participants per group (total of 82) would provide 80% power to detect a 2-point difference in GAD-7 total scores.

2.4.2 Feasibility and outcomes data analysis.—We calculated basic descriptive statistics to determine progress toward meeting feasibility goals and conducted ordinary

least squares (OLS) multiple regression²⁹ to determine the influence of PST on FCGs' anxiety, depression, and quality of life, using the last available measure post-baseline to compare group outcomes. Analyses were performed in R 3.5.0.³⁰ Beta coefficients and confidence intervals were estimated with a bootstrapping procedure, an analytic approach that has been considered non-parametric,³¹ where each estimate was generated based on 1,000 resamples.³² The regressor variable method was used in order to isolate the effect of the intervention (X) on participants' change scores ($Y_2 - Y_1$), where $Y_2 - Y_1$ was regressed on Y_1 and X.³³ Caregiver age, caregiver gender, patient's clinic attendance (received care from the specialty palliative care clinic: yes or no), whether the FCG provided care for more than one person with cancer (yes or no) or provided care in cooperation with another FCG enrolled in the study (yes or no), and the number of days FCGs who were ultimately lost to attrition remained in the study were included as covariates in each model to further elucidate the unique contribution of the intervention to participant change scores.

3. Results

Study and intervention feasibility were both supported. We met our recruitment goal one month early, enrolling 83 FCGs in 17 months (participant demographic information is summarized in Table 1). Approximately 75% of our sample was retained through 30-day follow-up. Treatment fidelity, which was calculated as the mean percentage of essential intervention elements observed in the sample of audio-recorded sessions, was 97%.

Preliminary analyses indicated that randomization produced equivalent groups in terms of key demographic variables and baseline outcome measures, which were also controlled for in subsequent modeling (see Table 2); no statistically significant differences were noted at baseline. Results from OLS modeling, which we conducted to determine if receipt of PST significantly predicted FCGs' anxiety, depression, and quality of life, are summarized in Table 2. Participants who received the PST intervention reported statistically significantly less anxiety ($p = .03$) than those receiving only usual care. No statistically significant differences were noted for caregiver depression ($p = .07$) or quality of life ($p = .06$).

4. Discussion

Data resulting from this feasibility study of a PST intervention for FCGs of patients with cancer receiving outpatient palliative care provide strong support for the feasibility of the intervention. In addition, the study generated preliminary efficacy data highlighting the potential of PST to decrease FCG anxiety, consistent with both pilot work and large-scale testing of PST interventions in different settings and populations.^{17,18,34,35} That neither change in quality of life nor depression were shown to differ between participants in the intervention and usual care groups is noteworthy primarily due to these findings' discordance with much of the published literature.³⁶ As with all outcomes assessed in this feasibility study, the effect of PST on FCGs' depression and quality of life should be investigated in future studies including a larger sample, particularly since power calculations for the present study were based solely on expected changes in anxiety.

4.1 Study Limitations

A number of other study limitations warrant attention. First, with regard to data analysis, the process of resampling via bootstrapping likely resulted in more robust confidence intervals than would otherwise have been generated, especially given the small sample included in this study,³² underscoring the need for future, large-scale research on the effect of PST for FCGs in outpatient palliative care. Second, the relatively homogenous nature of the study sample must be noted, as it limits the study's generalizability, particularly with regard to FCG race and ethnicity. Third, all FCG participants were recruited from the same healthcare facility; it is unknown whether similar results would be obtained in other settings. Fourth, the 60-day period of time FCGs were enrolled in the study is quite brief relative to the overall cancer trajectory for many individuals. The long-term impact of the PST intervention is therefore unknown. Fifth, allowing FCGs to choose whether to receive the intervention by telephone or web-based videoconferencing technology may have introduced unaccounted for variation in the intervention and/or its outcomes. Researchers conducting future studies of PST with FCGs should carefully weigh the potential advantages of this approach (e.g., facilitated recruitment of a difficult-to-reach study population, enhanced generalizability to include technologically-averse FCGs) against its limitations when making decisions regarding study design. Finally, given that PST has been repeatedly shown to be safe¹⁶ and that this was a preliminary trial likely to be replicated, relatively high error rates³⁷ and a one-tailed test of significance were deemed appropriate; however, lower error rates and a two-tailed test of significance should be employed in future large-scale testing.

4.2 Clinical Implications

Problem-solving therapy is a feasible and promising approach to reducing cancer family caregivers' anxiety; however, advocacy aimed at widespread adoption of PST for FCGs in outpatient palliative care would be premature. Additional testing is needed to provide data necessary to ensure responsible use of limited healthcare resources. In addition, given the limited number of outpatient specialty palliative care clinics currently in existence,¹³ providers may want to carefully consider whether FCG support services such as PST should originate in the palliative care clinic or be provided as a component of standard cancer care.

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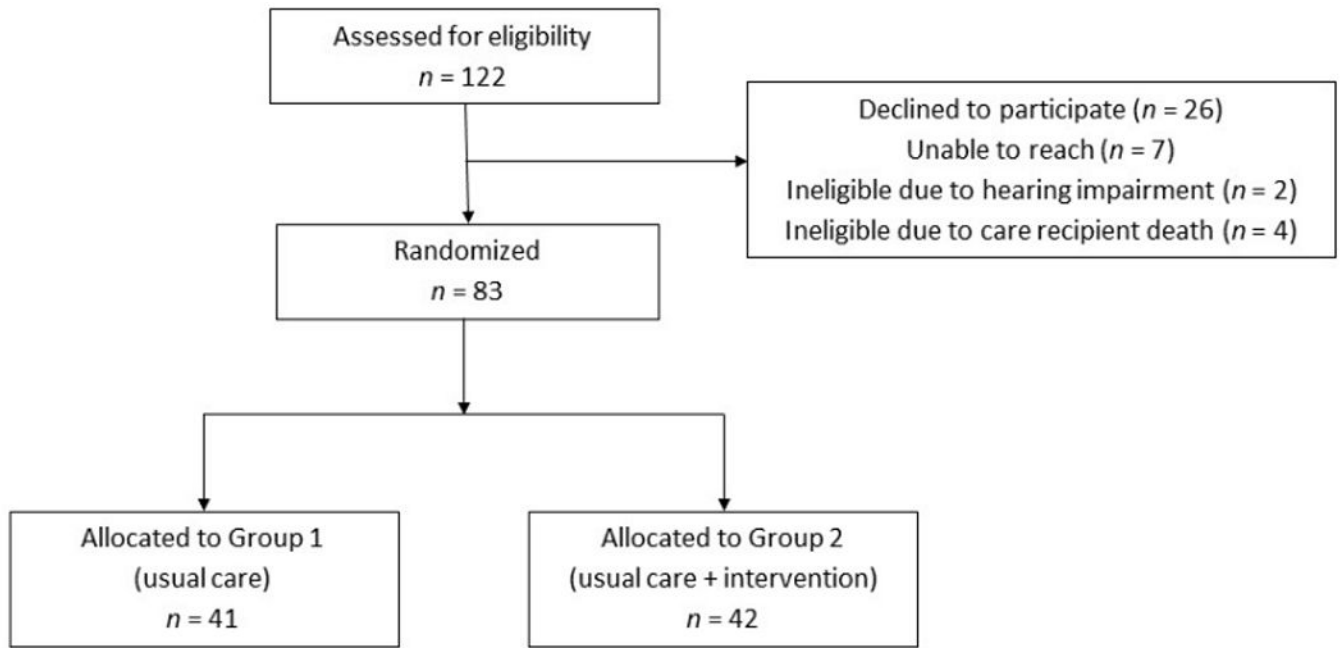


Figure 1.
CONSORT flow diagram

Table 1.

Caregiver and Patient Characteristics

Characteristic	No. (%) ^a	
	Caregivers	Patients
Gender		
Male	26 (31.3)	39 (47.0)
Female	57 (68.7)	44 (53.0)
Age, mean (<i>SD</i>)	51.5 (12.8)	60.4 (12.8)
Race		
African American/Black	2 (2.4)	5 (6.0)
Asian/Asian-American	1 (1.2)	1 (1.2)
Native American/American Indian	2 (2.4)	0 (0.0)
Caucasian/White	77 (92.8)	75 (90.4)
Multiracial	1 (1.2)	2 (2.4)
Ethnicity		
Latinx	1 (1.2)	4 (4.8)
Non-Latinx	82 (98.8)	79 (95.2)
Relationship to patient		
Spouse or Partner	44 (53.0)	-
Adult Child	22 (26.5)	-
Sibling	7 (8.4)	-
Parent	3 (3.6)	-
Friend	3 (3.6)	-
Other (e.g., adult grandchild, nephew)	4 (4.8)	-
Primary Cancer Site/Type ^b		
Blood	-	4
Brain	-	3
Breast	-	9
Colorectal	-	13
Gynecological	-	7
Head and Neck	-	4
Liver	-	6
Lung	-	15
Melanoma	-	4
Mesothelioma	-	3
Other	-	3
Pancreas	-	4
Prostate	-	3
Urinary Tract	-	5

^aDue to rounding, percentages might not sum to 100.

^bPer FCG report.

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Table 2Effect of the Problem-Solving Intervention on Family Caregiver Outcomes^a

	B	Std. Error	Sig. (2-tailed)	95% Confidence Intervals ^b	
				Lower	Upper
<i>Anxiety (GAD-7)</i>					
Constant	16.36	8.61	.115	-2.30	32.28
Group	-2.76	1.22	.03*	-5.18	-.30
GAD-7 Baseline Score	-.86	.13	.002	-1.10	-.60
<i>Depression (PHQ-9)</i>					
Constant	12.80	8.49	.20	-4.44	29.5
Group	-2.68	1.34	.07	-4.96	.21
PHQ-9 Baseline Score	-.50	.17	.01	-.82	-.144
<i>Quality of Life (CQLI-R)</i>					
Constant	-5.29	8.56	.61	-21.75	10.22
Group	2.77	1.39	.06	-.012	5.42
CQLI-R Baseline Score	-.49	.09	.002	-.66	-.28

Note:

^aBootstrap results are based on 1000 bootstrap samples;^bConfidence intervals based on 626 samples;

* statistically significant < .05 (denoted for outcome measures only).

All models controlled for family caregiver (FCG) age, FCG gender, patient's clinic attendance, multiple caregivers/care recipients, FCG number of days in study, and participants' baseline scores on respective outcome measures.