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Title

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Permalink

<https://escholarship.org/uc/item/5mx0h06d>

Journal

Journal of Pain and Symptom Management, 65(3)

ISSN

0885-3924

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Publication Date

2023-03-01

DOI

10.1016/j.jpainsymman.2022.11.025

Peer reviewed



Published in final edited form as:

J Pain Symptom Manage. 2023 March ; 65(3): 173–182. doi:10.1016/j.jpainsymman.2022.11.025.

Examining Caregiver Outcomes in the CONNECT Intervention for Patients with Advanced Cancer

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Abstract

Background: Palliative care offers patient and family centered approaches that may mitigate risk of caregiver burden and poor mood.

Objectives: To determine whether a palliative care intervention (CONNECT) improved burden, mood, and self-efficacy among caregivers of patients with advanced cancer.

Intervention: In this cluster randomized trial, patients and their caregivers were recruited from 17 Oncology clinics in Pennsylvania. Participants attended nurse-led monthly visits, addressing patient symptoms, goals of care, and advance care planning.

Measurements: At baseline and 3 months, we measured caregiver burden using Zarit Burden Interview (ZBI-12; range 0–48), caregiver anxiety and depression using Hospital Anxiety and

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Author Contributions

Study concept and design: Schenker, Arnold, White, Smith, Chu; Acquisition of subjects and/or data: Schenker, Althouse, Arnold, White, Smith, Chu; Analysis and interpretation of data: Althouse, Semere, Schenker; Preparation of manuscript: Semere, Althouse, Arnold, White, Smith, Chu, Rosenzweig, Schenker.

Conflicts of Interest

The authors have no conflicts of interest to disclose.

Depression Scales (HADS-A, range 0–21; HADS-D, range 0–21). We measured caregiver self-efficacy at 3 months using Caregiver Inventory (CGI; range 0–189).

Outcomes: We enrolled 441 caregivers and 381 completed 3-month assessments. We found no significant differences in caregiver burden (adjusted mean difference -0.39 ; 95% CI -1.07 to 0.29 , $p = 0.90$), depression (adjusted mean difference -0.22 , 95% CI -0.97 to 0.55 , $p = 0.26$), or anxiety (adjusted mean difference 0.09 ; 95% CI -1.25 to 1.43 , $p = 0.58$), between the intervention and standard care at 3 months. Caregiver self-efficacy was higher at 3 months in the intervention compared to standard care (adjusted mean difference 9.36 ; 95% CI 0.95 to 17.77 , $p = 0.030$).

Conclusions: Caregivers in CONNECT did not experience improved burden or mood, however, they reported higher self-efficacy compared to caregivers receiving standard care. This study highlights the need for strategies to optimize caregiver outcomes in palliative care interventions.

Keywords

caregiver burden; advanced cancer; palliative care; caregiver mood; caregiver self-efficacy

Introduction

Family caregiver involvement is considered central to supporting complex care needs and treatment decisions for patients with advanced cancer.^(1–3) Caregivers, however, face significant strain as they navigate patient physical and emotional symptoms near the end of life.⁽⁴⁾ Demanding caregiving roles and lack of support for providing complex care, place caregivers at high risk for declining mood and high levels of burden.⁽⁵⁾ Caregiver self-efficacy is considered an important outcome in cancer care that can influence caregiving experiences for both caregivers and patients.^(6, 7)

Palliative care focuses on addressing patient symptom management, quality of life, and advance care planning through integrated patient and family caregiver-centered approaches.⁽⁸⁾ Historically, however, palliative care interventions even when including caregivers have targeted patient outcomes with less attention to caregiver outcomes, such as burden.⁽⁹⁾ While more recent studies demonstrate that early palliative care in advanced cancer facilitates coping strategies that improve patient outcomes such as quality of life and depression,^(10, 11) there continue to be limited studies regarding effects on caregiver outcomes.⁽¹²⁾ Among palliative care interventions focusing on patients and caregivers, a few studies suggest improved caregiver depression but remain inconclusive regarding burden.^(13–15) While some patient-caregiver dyadic interventions have demonstrated improvements in caregiver self-efficacy, others have found these effects are not sustained.^(16, 17) Further research is needed to better understand whether palliative care interventions can improve outcomes for caregivers at risk for burden, poor mood, and low self-efficacy.

Care management by Oncology Nurses to address supportive care needs (CONNECT) is an innovative nurse-led intervention, primarily directed towards patients with caregiver engagement encouraged in order to improve provision of primary palliative care within oncology practices. Nurses engage patients and caregivers in monthly visits to complete shared care plans addressing patient symptoms and establishing future treatment preferences

and goals. Patient and caregiver access to the potential benefits of palliative care remains challenging in part due to logistical health system challenges, including a limited number of specialists and provider time constraints.⁽¹⁸⁾ Patients and caregivers may have difficulty traveling to additional appointments and be hesitant to engage with new providers, which could hinder their palliative care engagement.⁽¹⁸⁾ We designed CONNECT to address these barriers and maximize convenience for patients and families by utilizing patient's current oncology clinic settings and involving familiar nurse providers.

We conducted a cluster randomized trial of the CONNECT intervention compared to standard care for patients with advanced cancer and their caregivers. We did not find an improvement in patient quality of life, which we previously described.⁽¹⁹⁾ Here, we report the effect of CONNECT on our main caregiver outcomes—burden and mood, and a secondary caregiver outcome, self-efficacy. We hypothesized that caregivers enrolled in the CONNECT intervention would experience lower levels of burden, less anxiety and depressive symptoms, and higher self-efficacy, compared to caregivers receiving standard care.

Methods

Study Design

This is a cluster randomized, controlled trial designed to compare the CONNECT (Care management by Oncology Nurses to address supportive care needs) intervention to standard care among patients with advanced cancer and their caregivers. Complete details of the study trial protocol and patient outcomes were previously published.⁽²⁰⁾ Here, we describe the effect of the CONNECT intervention on our main caregiver outcomes—burden and mood—and secondary caregiver outcome, self-efficacy. The study protocol was approved by the University of Pittsburgh Institutional Review Board (PRO15120154) and the trial is registered on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02712229) (NCT02712229).

Study Setting

Patients and their caregivers were recruited from 17 oncology practices within the University of Pittsburgh Hillman Cancer Center Network in Western Pennsylvania. The network provides care to over 30,000 patients each year, approximately 8% of whom are racial/ethnic minorities.

Study Participants

Patients were eligible for the study if they were ≥ 21 years old with a metastatic solid tumor, received ongoing oncologic care at a participating study site, and their oncologist “would not be surprised” if they died within a year.^(21, 22) Patients were excluded if they had Eastern Cooperative Oncology Group (ECOG) performance status of 3 (capable of only limited selfcare; confined to bed or chair more than 50% of waking hours) or 4 (completely disabled; totally confined to bed or chair).⁽²³⁾ Eligible patients were encouraged but not required to identify an adult caregiver (≥ 21 years) for study participation. Caregivers were defined as the “family member or friend most likely to accompany you to clinic visits or help with your care should you need it.” Caregivers were excluded if they were unable to

read and respond to questions in English or were unable to complete the baseline interview. All enrolled caregivers provided written or verbal informed consent. Patient and caregiver participants were compensated \$30 for completion of 3-month follow up assessments.

CONNECT Intervention

Oncology nurses received specialized training in primary palliative care to lead the delivery of the CONNECT intervention within oncology clinics. CONNECT visits occurred on a monthly basis for 3 months, before and/or after patients' regularly scheduled oncology clinic visits. Caregivers were invited, but not required, to accompany patients to each intervention visit. Nurses were instructed to engage the caregiver, if present, during key parts of the intervention visits. The goals of the first visit included establishing rapport with both the patient and caregiver, addressing patient symptoms, and helping the patient to choose a surrogate decision maker. Subsequent visits included a focus on working with both the patient and caregiver to establish future treatment preferences and goals, and complete an advance directive. During each visit patients and caregivers engaged in completing shared care plans to address symptom needs and advance care planning. Nurses specifically asked caregivers how they were coping with the patient's illness and provided emotional support. At the end of each visit, nurses were instructed to engage both patient and caregiver in "teach back" to ensure that there was common understanding about what occurred during the visit and next steps. Sessions lasted approximately 60 minutes; the first visit took place in-person and subsequent visits took place either in-person or by phone. After each intervention visit, the nurse checked in with the oncologist regarding the patient's symptoms, preferences, and goals. These check-ins could entail simple updates or more complex requests for medication changes or discussions about goals of care. Within 1 week of each visit, the nurse called the patient and invited the caregiver, if present, to review and discuss any problems with the visit plan.

Standard care

Typical practice at participating clinics involved oncology nurses assessing patient symptoms and administering treatments, including chemotherapy. Advance directives, although often available, are not routinely reviewed with patients and their families. Caregiver burden, mood, and self-efficacy are not typically assessed as part of standard oncology care.

Study Measures

Caregiver burden.—We assessed caregiver burden at baseline and 3-month follow up using the validated Zarit Burden Interview (ZBI) short version (ZBI-12). We did not conduct a follow-up assessment of burden for caregivers of patients who died prior to 3-month follow up. The ZBI is the most widely used instrument to assess subjective caregiver burden and has been examined extensively in caregivers of patients with cancer.⁽²⁴⁾ The shorter version, ZBI-12, correlates well with the full ZBI. Caregivers subjectively answer questions related to the impact of caregiving on their physical, emotional, and social well-being. Responses are reported on a 5-point Likert scale (0=Never to 4=Nearly Always) and total scores range

from 0 to 48, with higher scores indicating more burden. A ZBI-12 score greater than 12 has been shown to correlate well with high burden.⁽²⁵⁾

Caregiver anxiety and depression.—We assessed caregivers’ symptoms of anxiety and depression at baseline and at 3-month follow up using the Hospital Anxiety and Depression Score (HADS), a widely used instrument that has been extensively validated for measuring symptoms of emotional distress among caregivers. The HADS consists of two 7-item subscales that measure symptoms of anxiety (HADS-A) and depression (HADS-D); respondents rate presence of each symptom on a scale from 0 (absence) to 3 (extreme). Higher scores (HADS-A, range 0–21; HADS-D, range 0–21) indicate greater levels of anxiety or depression. A score greater than 7 on either subscale suggests clinically significant anxiety and depressive symptoms.^(26, 27)

Caregiver self-efficacy.—We used the Caregiver Inventory (CGI) to evaluate caregiver self-efficacy at 3-month follow up for caregivers of patients who were alive. We did not measure caregiver self-efficacy at baseline as this was a secondary outcome. The CGI is a reliable and validated measure of self-efficacy for caregiving that focuses on caregiver self-efficacy for navigating the demands of caregiving for care recipients with cancer. The instrument consists of 21 items that focus on 4 key domains (managing medical information, caring for the care recipient, caring for oneself, and managing difficult interactions and emotions); caregivers rate, on a 9-point Likert scale (1= “not at all confident” to 9= “totally confident”), their responses to questions that assess confidence in ability to perform caregiving duties in each domain, with higher scores indicating greater self-efficacy (CGI, range 0–189).⁽²⁸⁾

Additional caregiver characteristics.—We collected caregiver sociodemographic characteristics, including age, gender, race/ethnicity, partner status, income security, and education level. In addition, we asked caregivers about the context of their caregiving. Caregivers reported their relationship to the patient, whether they lived with the patient, hours per week spent caregiving, and the types of support provided (e.g. household chores, transportation, emotional and social support).

Patient characteristics.—For this study, we focused on describing select patient characteristics (cancer type and ECOG), which we hypothesized were particularly relevant to caregiver burden, mood, and self-efficacy.⁽²⁹⁾

Statistical Analysis

We used descriptive statistics (frequency, mean, standard deviation) to present caregivers’ sociodemographic characteristics and caregiving context. For patients and caregivers in the intervention arm who completed 3-month assessments, we described the frequency of intervention visits that each attended. We used multi-level random-intercept mixed-effect models, accounting for clinic clustering, to examine whether our main caregiver outcomes (burden, ZBI-12; mood, HADS-A and HADS-D) and secondary caregiver outcome (self-efficacy, CGI), were significantly different in the intervention group compared to the standard care group. We conducted a complete case analysis, adjusting our models for

caregiver characteristics (age, gender, education, income security, baseline burden, and baseline mood symptoms) and patient characteristics (ECOG, cancer type). We conducted a secondary intensity-adjusted analysis estimating treatment effect by number of visits the caregiver attended. We created a covariate for the number of CONNECT visits attended before the 3-month assessment (0 for all caregivers randomized to the standard care group, and number of visits attended before the 3-month assessment for caregivers randomized to the CONNECT group) and divided this by the total number of possible visits, 3.

We conducted a subgroup analysis, restricted only to caregivers with higher baseline mood (HADS-D>7, HADS-A>7) and burden (ZBI-12>12) symptoms, examining regression-estimated differences in each of the caregiver outcomes (burden and mood) between intervention and standard care groups. We adjusted for the same caregiver and patient characteristics as in our main analysis. A two-sided p -value <0.05 was considered to be statistically significant. We performed all statistical analyses using SAS version 9.4 (SAS Institute, Cary, NC).

Results

Caregiver and caregiving context baseline characteristics

In total, 672 patients enrolled in the CONNECT trial, 441 of whom had an accompanying caregiver enroll (233 patients with caregivers were allocated to the intervention arm and 208 patients with caregivers were allocated to the standard care arm). (Figure) The mean age of enrolled caregivers was 61 years, 73% were women and the majority white (95%). More than three-fourths (77%) of caregivers were married and most were retired (44%).

At baseline, caregivers' mean Zarit burden score was low at 10.3 (\pm 7.3), HADS-D score was high at 7.27 (\pm 4.20), and HADS-A score was low at 4.51 (\pm 3.71). Most caregivers (59%) were caring for a spouse or partner and many were living with their care recipient (69%). Lung cancer was the most common cancer among care recipients (38%) and 21% had an ECOG of 2, indicating the care recipient was capable of selfcare but unable to carry out work activities. Caregivers reported providing on average 44.5 (\pm 53.5) hours of care weekly. Caregivers reported helping patients with a number of tasks, most frequently emotional and/or social support (92%) and medical care (89%). (Table 1)

Attendance at CONNECT intervention visits

Patients and caregivers enrolled in the intervention arm attended intervention visits to varying degrees (Table 2). Of the 206 patients with an enrolled caregiver who completed a 3-month assessment, 92 (45%) attended all three scheduled intervention visits, 38 (19%) attended two intervention visits, 33 (16%) attended one intervention visit, and forty-five (21%) did not attend any intervention visits. There were 385 patient-attended intervention visits, of which the caregiver was present for 231 (60%).

Caregiver outcomes

Of the 441 enrolled caregivers, 381 completed 3-month assessments (response rate = 86%). When comparing caregivers who completed 3-month assessments in the intervention arm

to caregivers who completed 3-month assessments in the standard care arm, there was not a decrease in mean burden scores (adjusted mean difference -0.39 ; 95% CI -1.07 to 0.29 , $p = 0.90$), depressive symptoms (adjusted mean difference -0.22 , 95% CI -0.97 to 0.55 , $p = 0.26$), or anxiety symptoms (adjusted mean difference 0.09 ; 95% CI -1.25 to 1.43 , $p = 0.58$). (Table 3) Caregivers of patients in the intervention arm did, however, report higher self-efficacy at 3 months than caregivers of patients in the standard care arm (adjusted mean difference 9.36 , 95% CI 0.95 to 17.77 , $p=0.03$).

Sensitivity/Subgroup Analyses

In the intensity-adjusted analysis, there was no suggestion that caregivers who attended more intervention visits experienced lower burden scores ($p = 0.95$), less depressive symptoms ($p = 0.91$), or anxiety symptoms ($p = 0.27$). (Supplement A) In the subgroup analyses, restricting the sample to caregivers with baseline higher levels of depressive symptoms (HADS-D >7 ; $n = 179$), anxiety symptoms (HADS-A >7 ; $n = 75$), and caregiver burden (ZBI-12 >12 ; $n = 108$), there were no significant differences between the intervention and standard care groups in burden ($p = 0.88$), depressive ($p = 0.19$), and anxiety ($p = 0.79$) symptoms at 3-months. (Supplement B)

Discussion

In a cluster-randomized controlled trial of a primary palliative care intervention, we found that caregivers of patients with advanced cancer in the intervention arm did not experience less burden or better mood compared to those in the standard care arm. However, caregivers in the intervention arm reported higher self-efficacy at 3 months than caregivers in the standard care arm.

Our findings are consistent with previous patient-focused palliative care interventions that have failed to demonstrate benefits for involved caregivers.^(30, 31) The lack of improvement we found in patient outcomes as a result of the intervention⁽¹⁹⁾ could explain the lack of improvement in caregiver burden and mood. In an early integrated palliative care intervention, focused on patients with lung and gastrointestinal cancer, El-Jawahri et al. found improved patient outcomes and caregiver psychological symptoms.⁽¹⁴⁾ However, several prior studies suggest that improving patient outcomes alone may not be enough to improve caregiver outcomes. For example, the ENABLE II intervention led to improvements in patient mood and quality of life, but did not improve caregiver burden.⁽¹⁵⁾ Similarly, the palliative care intervention led by Clark et al. demonstrated improvements in patients' quality of life but not in caregiver burden.⁽³¹⁾ Patients and caregivers may differ in the timing and manifestation of their emotional response to stressors in cancer care, particularly during critical events such as treatment.⁽³²⁾ These differences in patient and caregiver experiences create challenges in focusing patient-facing interventions in such a way as to improve caregiver outcomes. Targeting intervention implementation to the right group at the right time may be most important in effecting caregiver outcomes.

There are five potential reasons that we believe may explain why our intervention failed to improve caregiver burden and mood. First, training for nurses delivering CONNECT primarily focused on addressing patient needs and secondarily focused on offering support

to caregivers. Nurses, therefore, may not have felt adequately equipped to recognize or support the needs of burdened or psychologically distressed caregivers. In a recent national survey of Oncology Nursing Society members, nurses reported low confidence in assessing and intervening to address caregiver burden, revealing the need for training primarily focused on increasing nurses' knowledge and confidence in supporting caregiver needs.⁽³³⁾ Caregiver interventions have demonstrated that coaching and skill-based strategies targeting caregivers of patients with cancer can improve caregiver burden and mood. Incorporating these skill-based approaches within the intervention, may have yielded benefits for caregiver outcomes.^(34–36) Second, the duration of CONNECT visits may not have allowed adequate time to identify and address caregiver symptoms of burden and poor mood. Several prior studies demonstrate that lack of time is a significant limiting factor for clinicians attempting to support caregiver needs.^(33, 37, 38) Third, low rates of caregiver attendance at CONNECT visits may have limited opportunities for potential benefits from the intervention. However, we conducted a dose response analysis that did not reveal evidence that caregivers who attended more intervention visits had improved outcomes. Fourth, given caregiver baseline burden and anxiety symptoms were low, there may have been less opportunity for improvement in these outcomes at the end of the intervention. Caregivers in our sample were of older age, and prior work has suggested that older caregivers for cancer patients experience less burden than younger caregivers.^(39, 40) However, in our subgroup analyses restricted to caregivers with higher baseline burden and mood, we similarly did not find improvements. Fifth, while we chose to design CONNECT intervention visits to take place before or after patients' routine oncology appointments to limit the burden of additional visits, this may have been a challenging environment for caregivers to engage in discussions around their own needs. Caregivers may have been reluctant to draw focus away from patient treatment. Caregivers may also have been hesitant to discuss experiencing high burden and poor mood related to their caregiving responsibilities in front of patients, who could in turn feel responsible for the challenges of the caregiving situation.

We found that, at 3 months, caregivers in the intervention group experienced higher self-efficacy compared to caregivers in the standard care group. Our intervention prioritized engaging caregivers in patients' care plans, which may have facilitated better caregiver understanding of patient symptoms and greater caregiver confidence in their ability to manage patients' needs. The overall family-centered approach in palliative care may offer a unique opportunity to empower caregivers. While we cannot conclude that the change we observed in caregiver self-efficacy is clinically significant, caregiver self-efficacy is associated with several important caregiver and patient outcomes.^(6, 7) Caregivers with high self-efficacy demonstrate confidence in performing caregiving duties and managing patients' symptoms that can not only improve the quality of care that they provide but may be protective against high levels of caregiver burden and poor mood.⁽⁶⁾ Among patients with lung cancer, high caregiver self-efficacy has been associated with improved patient physical and emotional well-being.⁽⁷⁾

Our findings suggest important considerations for improving caregiver outcomes in future palliative care interventions. We propose that incorporating provider training and opportunities to address caregiver needs specifically within patient-facing interventions is key to improving caregiver outcomes. Delivering interventions in a context that is

both convenient for patient and caregiver participation, while considering a supportive environment for caregivers to engage in discussing their own needs must also be considered.

Our study has important limitations. We excluded patients with very poor performance status (ECOG 3 and 4). Our study is restricted to oncology clinics in Western Pennsylvania, that serve largely white and low to middle socioeconomic status patients. We restricted participation to English-speaking participants, the vast majority of whom identify as white race. Therefore, our findings may not generalize to caregivers of patients with worse performance status or from racially and ethnically diverse populations. Prior studies suggested that important differences exist in cancer caregiving experiences across race and ethnicity, including experiences of discrimination, substandard access to services and treatment, language and cultural barriers.⁽⁴¹⁾ It is important to note that we did not measure caregiver self-efficacy at baseline as this was a secondary outcome and we opted to exclude these questions to minimize caregiver survey burden. While it is possible that at baseline caregivers in the intervention arm experienced significantly higher self-efficacy compared to caregivers in the standard care arm, the randomization of participants makes this unlikely.

In conclusion, we found that a patient-directed palliative care intervention that engaged caregivers did not improve caregiver burden and mood, however, caregivers experienced higher self-efficacy. Given caregivers' important roles in supporting patients with advanced cancer, it is critical that we identify interventions that can optimize caregiver outcomes. Future efforts should focus on training providers to address caregiver needs within patient-directed palliative care interventions and fostering a supportive environment for caregiver involvement.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Funders:

This work was supported by a grant from the National Cancer Institute (R01CA19703), the University of Pittsburgh Cancer Institute (P30CA047904) and the Palliative Research Center (PaRC). Dr. Schenker is supported by a National Institutes of Aging award (K24AG070285). Dr. Semere was supported by an Agency for Healthcare Research and Quality award (K08HS27844). The sponsors had no role in the data collection, analysis or writing of the manuscript. The contents and views in this manuscript are those of the authors.

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Key Message:

We describe a cluster randomized palliative care intervention involving patients with advanced cancer and their caregivers. Our results did not demonstrate improved caregiver burden or mood, but showed higher caregiver self-efficacy at the intervention end. This work highlights opportunities to optimize palliative care interventions to identify and address caregiver needs.

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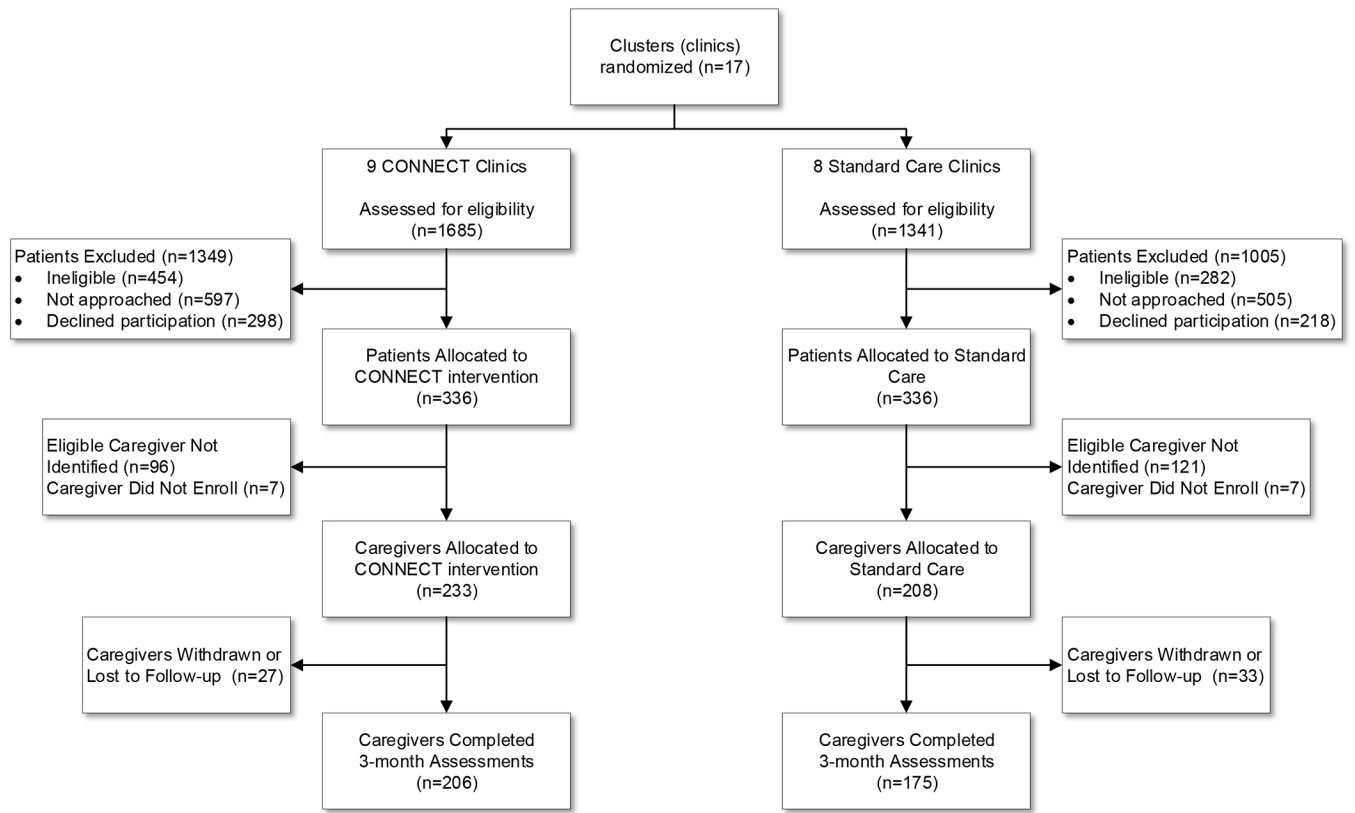


Figure 1. The CONSORT diagram shows patient and family caregiver enrollment.

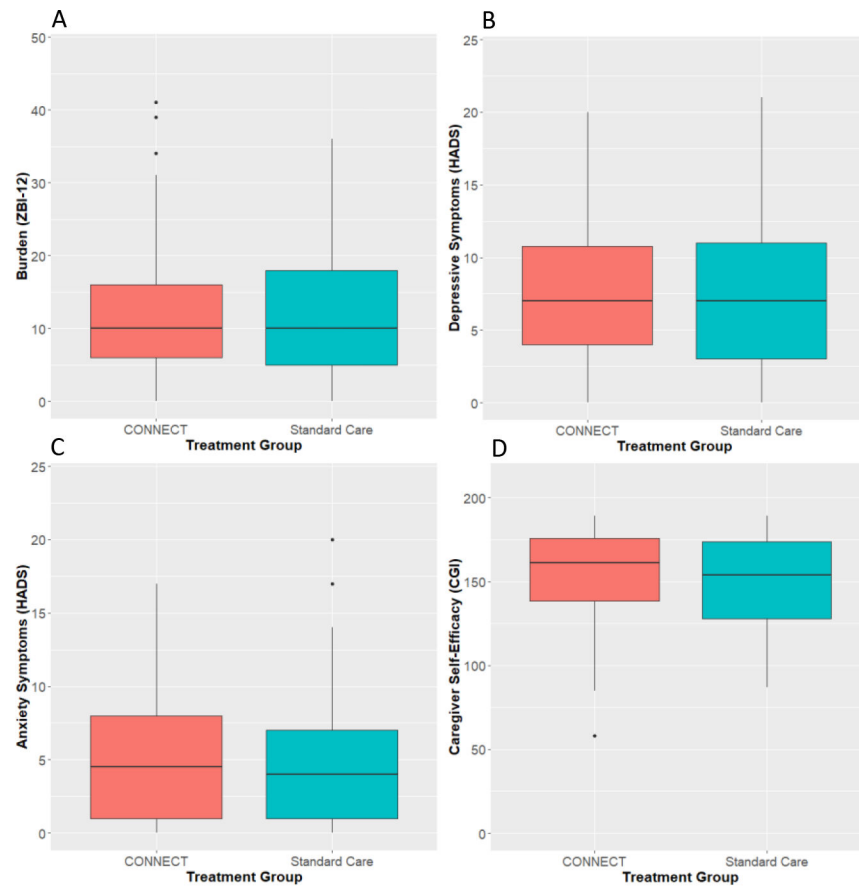


Figure 2.

The figure shows caregiver scores for each study outcome at 3 months by caregiver treatment group (CONNECT vs Standard Care): A. Burden (adjusted mean difference -0.39 ; 95% CI -1.07 to 0.29 , $p = 0.90$); B. Depressive symptoms (adjusted mean difference -0.22 , 95% CI -0.97 to 0.55 , $p = 0.26$); C. Anxiety symptoms (adjusted mean difference 0.09 ; 95% CI -1.25 to 1.43 , $p = 0.58$); D. Self-efficacy (adjusted mean difference 9.36 , 95% CI 0.95 to 17.77 , $p = 0.03$).

Table 1.

Baseline characteristics of enrolled caregivers and caregiving context (n=441)

| | Full Trial Population No. (%) | CONNECT No. (%) | Standard Care No. (%) |
|--|-------------------------------------|--------------------|--------------------------|
| Caregiver characteristics | 441 | 233 | 208 |
| Age, mean \pm SD | 61.5 \pm 13.3 | 60.4 \pm 13.4 | 62.7 \pm 13.1 |
| Women | 322 (73.0) | 176 (75.5) | 146 (70.2) |
| Race | | | |
| Caucasian/White | 420 (95.2) | 222 (95.3) | 198 (95.2) |
| African-American/Black | 16 (3.6) | 7 (3.0) | 9 (4.3) |
| Asian | 1 (0.2) | 0 | 1 (0.5) |
| Other | 3 (0.7) | 3 (1.3) | 0 |
| Ethnicity | | | |
| Hispanic | 6 (1.4) | 3 (1.3) | 3 (1.4) |
| Education | | | |
| Less than high school | 15 (3.4) | 10 (4.3) | 5 (2.4) |
| High school diploma or GED | 157 (35.6) | 96 (41.2) | 61 (29.3) |
| Some college, no degree | 65 (14.7) | 28 (12.0) | 37 (17.8) |
| 2-year (Associate) degree | 79 (17.9) | 43 (18.5) | 36 (17.3) |
| 4-year (Bachelor's) degree | 79 (17.9) | 35 (15.0) | 44 (21.2) |
| Master's degree (MA, MS, MSW) | 37 (8.4) | 19 (8.2) | 18 (8.7) |
| Professional school (MD, DDC) | 3 (0.7) | 2 (0.9) | 1 (0.5) |
| Doctorate degree (PhD, EdD) | 2 (0.5) | 0 | 2 (1.0) |
| Declined to Answer | 2 (0.5) | 0 | 2 (1.0) |
| Married | 342 (77.6) | 176 (75.5) | 166 (79.8) |
| How well are you able to manage on your income? | | | |
| Can't make ends meet | 20 (4.5) | 14 (6.0) | 6 (2.9) |
| Just manage to get by | 112 (25.4) | 63 (27.0) | 49 (23.6) |
| Have enough with a little extra | 189 (42.9) | 94 (40.3) | 95 (45.7) |
| Money is not a problem | 82 (18.6) | 47 (20.2) | 35 (16.8) |
| Declined to Answer | 36 (8.2) | 14 (6.0) | 22 (10.6) |
| Depressive symptoms (HADS-D), mean \pm SD | 7.27 \pm 4.20 | 7.49 \pm 4.23 | 7.03 \pm 4.16 |
| Anxiety symptoms (HADS-A), mean \pm SD | 4.51 \pm 3.71 | 4.52 \pm 3.70 | 4.50 \pm 3.73 |
| Caregiver burden (Zarit burden score), mean \pm SD | 10.3 \pm 7.3 | 10.5 \pm 7.3 | 10.0 \pm 7.3 |
| Caregiving context | | | |
| Relationship to the patient | | | |
| Spouse/Partner | 261 (59.2) | 128 (54.9) | 133 (63.9) |
| Child | 111 (25.2) | 60 (25.8) | 51 (24.5) |
| Parent | 4 (0.9) | 2 (0.9) | 2 (1.0) |
| Sibling | 27 (6.1) | 19 (8.2) | 8 (3.8) |
| Other relative | 20 (4.5) | 15 (6.4) | 5 (2.4) |

| | Full Trial Population No. (%) | CONNECT No. (%) | Standard Care No. (%) |
|--|----------------------------------|--------------------|--------------------------|
| Friend | 15 (3.4) | 8 (3.4) | 7 (3.4) |
| Co-residing with patient | 305 (69.2) | 153 (65.7) | 152 (73.1) |
| Primary cancer type of patient | | | |
| Genitourinary | 44 (10.0) | 22 (9.4) | 22 (10.6) |
| Brain | 1 (0.2) | 1 (0.4) | 0 |
| Breast | 46 (10.4) | 21 (9.0) | 25 (12.0) |
| Gynecologic | 18 (4.1) | 12 (5.2) | 6 (2.9) |
| Gastrointestinal | 89 (20.2) | 42 (18.0) | 47 (22.6) |
| Hepatobiliary | 58 (13.2) | 34 (14.6) | 24 (11.5) |
| Head and Neck | 9 (2.0) | 5 (2.1) | 4 (1.9) |
| Lung | 166 (37.6) | 93 (39.9) | 73 (35.1) |
| Melanoma | 6 (1.4) | 3 (1.3) | 3 (1.4) |
| Sarcoma | 3 (0.7) | 0 | 3 (1.4) |
| Other | 1 (0.2) | 0 | 1 (0.5) |
| Patient performance Status (ECOG) | | | |
| 0=Fully Active | 89 (20.2) | 30 (12.9) | 59 (28.4) |
| 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature | 260 (59.0) | 152 (65.2) | 108 (51.9) |
| 2=Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours | 92 (20.9) | 51 (21.9) | 41 (19.7) |
| Hours per week spent caregiving, mean \pm SD | 44.5 \pm 53.5 | 43.3 \pm 51.6 | 45.8 \pm 55.6 |
| Type of care or support provide for the patient* | | | |
| Emotional and/or social support | 404 (91.6) | 211 (90.6) | 193 (92.8) |
| Medical care | 391 (88.7) | 206 (88.4) | 185 (88.9) |
| Household chores | 370 (83.9) | 195 (83.7) | 175 (84.1) |
| Transportation | 363 (82.3) | 198 (85.0) | 165 (79.3) |
| Handling finances | 261 (59.2) | 136 (58.4) | 125 (60.1) |
| Pet care | 150 (34.0) | 87 (37.3) | 63 (30.3) |
| Getting around the house | 138 (31.3) | 70 (30.0) | 68 (32.7) |
| Walking, transferring, or climbing stairs | 127 (28.8) | 68 (29.2) | 59 (28.4) |
| Bathing, dressing, grooming | 125 (28.3) | 63 (27.0) | 62 (29.8) |
| Caring for other people for whom the patient was providing care | 66 (15.0) | 44 (18.9) | 22 (10.6) |
| Using the bathroom | 49 (11.1) | 30 (12.9) | 19 (9.1) |
| Toileting | 46 (10.4) | 24 (10.3) | 22 (10.6) |
| Feeding | 30 (6.8) | 17 (7.3) | 13 (6.3) |
| Other | 20 (4.5) | 12 (5.2) | 8 (3.8) |

Continuous variables presented as mean \pm SD; categorical variables presented as frequency and percentage; percentages are based on non-missing values

Abbreviations: ECOG, Eastern Cooperative Oncology Group performance status; HADS-D, Hospital Anxiety and Depression Score – Depression subscale; HADS-A, Hospital Anxiety and Depression Score – Anxiety subscale

* Respondents check all that apply

Table 2.

Number of CONNECT visits caregivers attended by patient visits attended *

| | Among caregivers completed 3-month assessment (n=206) | | Among caregivers that completed 3-month assessment with patient still alive (n=158) | |
|---------------------------|--|-------------------------------|--|-------------------------------|
| | Patient attended No. (%) | Caregiver attended No. (%) | Patient attended No. (%) | Caregiver attended No. (%) |
| Patient attended 3 visits | 92 (44.7) | | 80 (50.6) | |
| Caregiver attended 3 | | 37 (18.0) | | 36 (22.8) |
| Caregiver attended 2 | | 15 (7.3) | | 14 (8.9) |
| Caregiver attended 1 | | 21 (10.2) | | 21(13.3) |
| Caregiver attended 0 | | 19 (9.2) | | 19 (12.0) |
| Patient attended 2 visits | 38 (18.5) | | 32 (20.3) | |
| Caregiver attended 2 | | 19 (9.2) | | 15 (9.5) |
| Caregiver attended 1 | | 10 (4.9) | | 9 (5.7) |
| Caregiver attended 0 | | 9 (4.4) | | 8 (5.1) |
| Patient attended 1 visit | 33 (16.0) | | 18 (11.4) | |
| Caregiver attended 1 | | 21 (10.2) | | 11 (7.0) |
| Caregiver attended 0 | | 12 (5.8) | | 7 (4.4) |
| Patient attended 0 visits | 43 (20.9) | 43 (20.9) | 18 (11.4) | 18 (11.4) |

* the number of CONNECT intervention visits that patients attended are shown with the corresponding number of visits where their caregiver was also in attendance.

Table 3.

Regression-Estimated Differences in Caregiver Outcomes Between Groups

| | CONNECT | Usual Care | Adjusted Mean Difference [¶] | p-value | ICC |
|--|--------------|--------------|---------------------------------------|---------|-------|
| Caregiver Self-efficacy (CGI) [*] | 155.6 ± 25.1 | 149.6 ± 28.1 | 9.36 (0.95, 17.77) | 0.030 | 0.050 |
| Depressive symptoms (HADS-D) [†] | 7.3 ± 4.5 | 7.4 ± 4.9 | -0.39 (-1.07, 0.29) | 0.258 | 0.005 |
| Anxiety symptoms (HADS-A) [‡] | 4.9 ± 3.9 | 4.9 ± 4.2 | -0.22 (-0.97, 0.55) | 0.578 | 0.018 |
| Burden (ZBI-12) [§] | 11.7 ± 8.5 | 11.9 ± 8.4 | 0.09 (-1.25, 1.43) | 0.900 | 0.023 |

^{*} Complete Case Analysis: N=304 (158 CONNECT +146 Standard care); only completed if patient still alive at time of caregiver's three-month assessment

[†] Complete Case Analysis: N=381 (206 CONNECT +175 Standard care)

[‡] Complete Case Analysis: N=378 (203 CONNECT +175 Standard care)

[§] Complete Case Analysis: N=303 (157 CONNECT +146 Standard care); only completed if patient still alive at time of caregiver's three-month assessment

[¶] adjusted for select caregiver and caregiving context characteristics (baseline score, age, gender, education, income security, patient cancer type, patient ECOG) and random effect for clinic; CGI is not adjusted for baseline score since this instrument was only collected at 3 months