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The Integration of Early Palliative Care With Oncology Care: The Time Has Come for a New Tradition

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Abstract

The past decade has brought forth innovative research that questions the traditional oncology care model for patients with advanced cancer. Through integrating palliative care (PC) early into the disease course for patients with a poor-prognosis cancer, 3 seminal studies showed improvements in outcomes, ranging from quality of life, mood, patient satisfaction, prognostic understanding, health service use, and possibly survival. The results of these paradigm-changing studies generate questions about the mechanisms through which early PC improves patient outcomes and about how best to disseminate early PC models. This article reviews the 3 studies, examines challenges to conducting PC research, and considers future directions in the field.

Patients with advanced, incurable cancers often experience a tremendous symptom burden, emotional and spiritual suffering, and a decline in their quality of life (QOL) over the course of disease.^{1–5} Traditionally, oncologists are at the center of their care, guiding treatment decisions, with a particular focus on using chemotherapy to control the cancer for as long as possible. This traditional care model has been successful in both prolonging patients' lives and ameliorating their symptom burden.^{6,7} Recently, a remarkable increase has occurred in the understanding of the biology of different cancers and in the number of new drugs available that target this biology.^{8,9} These complexities in cancer therapeutics have led to increased demands on oncologists' time during an ongoing workforce shortage of oncologists in some geographic areas, and an increasing number of patients with cancer and survivors of cancer. Despite these medical advances, patients continue to experience physical and psychological distress that is not always well addressed by their oncologists.^{2,10–13} These patients often spend many days in the oncology clinic for treatment and symptom management, and are hospitalized frequently for medical complications related to cancer.^{14–16} Additionally, it is becoming more common for patients with cancer to receive chemotherapy near the end of life (EOL) and to be referred to hospice late in the course of illness, which can be detrimental to patients and their family members.^{16–19} It can be a daunting task for oncologists to present patients' treatment options and potential side effects comprehensively and effectively, especially with the complexities of targeted therapy and clinical trials, while still having ample time to address

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the myriad supportive care needs of patients, their understanding of their disease and treatment, and their EOL care preferences.

In recent years, investigators have studied a novel approach: integrating specialty palliative care (PC) early in oncology care to better address supportive care needs. Specialty PC clinicians can include physicians, nurses, social workers, and chaplains. Three models have been described to deliver outpatient PC services: standalone, co-located, and fully embedded clinics that allow for comanagement of patients between PC and oncology.² With each of these models, PC clinicians work as a team to focus care on patients' supportive care needs, including physical and psychological symptoms, prognostic understanding, coping, decision-making about cancer treatment, and care at EOL, while communicating closely with the oncology team.²⁰ They also provide support and care to family members. Thus, integrating PC within oncology care has the potential to address some of the gaps in the traditional oncology care model by allowing PC clinicians to share in the complex tasks necessary to provide comprehensive care to patients with advanced cancer and their families.

In the past 5 years, 3 well-conducted, randomized, controlled studies have shown the benefits of an early integrated PC model for patients with advanced cancer.^{21–23} This article reviews the designs and results of the 3 studies that support the novel approach of integrating early PC within oncology care, explores barriers to the integrated care model, and concludes with future research directions.

Three Randomized Controlled Trials of an Early Integrated PC Model

The WHO defines PC as “an approach that improves the QOL of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.”²⁴ In contrast to hospice care, PC can be provided to patients at any point in their disease trajectory, irrespective of prognosis. PC can also be provided in conjunction with cancer therapies, such as chemotherapy or radiation, whether the goal of treatment is cure, palliation of symptoms, or prolongation of survival. Many comprehensive cancer centers have specialty PC teams, although they are most commonly called upon in the hospital setting, and often not consulted until late in a patient's disease course.^{12,25–27}

Three recent trials (Figure 1) demonstrated the benefits of early PC integrated with cancer care in the ambulatory setting. These trials capitalized on the benefits noted in earlier trials of PC in the hospital or home settings, but began the PC services earlier in the course of disease to maximize patients' QOL and care for as long as possible.^{28,29} Bakitas et al²¹ conducted a randomized trial of a psychoeducational intervention consisting of 4 weekly structured telephone sessions in patients with a new diagnosis of gastrointestinal, genitourinary, lung, or breast cancers with a prognosis of 1 year or less. PC-trained advanced practice nurses administered the sessions, which were followed by monthly phone communication until death. Outcome measures included QOL, mood, and health service use. Temel et al²² conducted a randomized study of a comanagement, fully embedded, outpatient PC model in patients with a new diagnosis of advanced non–small cell lung cancer. The

intervention entailed monthly outpatient PC visits throughout the patients' illness. Outcome measures included QOL, mood, prognostic awareness, and health service use. Zimmermann et al²³ conducted the most recent randomized study of a comanagement outpatient PC model. Unlike the Temel et al²² study, this trial included patients with various cancers, as long as they had a prognosis of 6 to 24 months. Outcome measures included QOL, symptom burden, and quality of EOL care.

Table 1 summarizes the results from the 3 trials, with attention to similarities and differences. Across various patient-reported outcome measures, the studies showed that, compared with patients receiving standard oncology care, those assigned to integrated PC experienced improvements in QOL and depression. The studies included several additional outcome measures, with one showing an improvement in patient satisfaction and a higher use of PC-based referrals in the hospital, nursing home, and home care setting, whereas another showed enhanced prognostic understanding and earlier referrals for hospice care with the integrated care model.^{22,23}

Challenges and Barriers of Early Integrated PC Research

This research answers many questions about how to provide optimal supportive care to patients with advanced cancer, but 2 questions arise regarding PC research methodology and dissemination. First, how do these studies differ from previous research in the field and what can be learned from their successes? Second, what barriers exist to the integration of PC into the care of patients with cancer?

Three reviews of the published literature highlight the mixed results of previous PC interventions and the many challenges investigators face when conducting this type of research.^{3,30,31} One review included 22 randomized studies, of which only 4 of 13 showed a significant difference in QOL, 1 of 14 showed an improvement in symptoms, 1 of 7 showed impacted cost, and 7 of 10 showed increased family satisfaction with care for the PC intervention arms. A second review included 44 studies evaluating the provision of palliative and hospice care teams, which overall showed only a slightly positive effect on patient outcomes, with the benefit strongest for studies integrating home-based care interventions. The third review by El-Jawahri et al³ emphasized similar mixed results. Overall, the interventions in all of the studies reviewed were highly variable in their focus, setting, and provision of care, ranging from psychosocial counseling, home care visits, outpatient nurse follow-up, and hospice facilities, to PC consultations in the outpatient, inpatient, and home settings. The authors cited many possible reasons for a lack of observed benefit in some outcome measures. Difficulties with study design including referral bias, insufficient power because of missing data or attrition intrinsic to the terminally ill population, and either failure to identify a primary outcome measure or use of measures that were not validated for the study population.

The challenges noted in previous studies provided an important foundation on which the investigators designed the 3 current trials. All 3 studies screened potentially eligible patients through clinic schedules or tumor boards, rather than relying on clinician referral to minimize enrollment bias. They were also all powered to examine prespecified, validated,

primary outcome measures, and the analysis plans accounted for missing data. Additionally, all 3 research groups began with a feasibility study of their respective interventions to further define the issues that could arise at their institutions before rolling out a randomized study.³²⁻³⁴ Given that PC has faced challenges with acceptance and integration, these pilot studies allowed the oncology and PC clinicians to gain experience working together and to develop relationships and rapport, which likely contributed to the success of the randomized studies.

Despite the improvements demonstrated in patients' QOL, mood, and prognostic understanding with early, integrated PC, many barriers remain to PC involvement in the care of patients with advanced cancer. One reason that clinicians do not refer patients is their misperception that PC is equivalent to EOL care, and their concern that patients and families will be alarmed by a referral.^{2,12,26,27,35,36} One survey showed that almost 60% of clinicians thought PC was synonymous with hospice and EOL care.³⁵ In another survey, only 37% of respondents believed they had access to PC services that accepted patients receiving chemotherapy.²⁶ Additionally, evidence shows that clinicians may underrecognize patient symptoms and concerns that might benefit from PC referral, and have intrinsic bias about certain cancers or symptoms that could influence their treatment decisions and referral practices.^{37,38} One study revealed significant differences in the reason for referral between those referred to PC services by a treating clinician and those identified via a comprehensive screening system, indicating that physicians may not recognize specific situations in which referral to PC may be beneficial.³⁷ Another study showed differences in clinicians' perceptions of symptoms and QOL of patients with lung cancer compared with those with other solid tumors. Other clinician barriers to more widespread use of PC include a belief that they are responsible for providing all of the necessary care for patients with cancer, doubt of the benefit of PC, and previous negative experiences with PC.^{11,12,39} These experiences with and misperceptions of the role of PC in combination with physicians' perceptions of patients' symptoms and experiences may prevent the wider acceptance of PC.³⁹ In addition, some evidence shows that patients may not want a PC referral even if offered, which could also further limit PC integration.³⁷

PC is also a relatively new field, with its introduction as a board specialty in 2006.⁴⁰ Most currently practicing clinicians were trained before its introduction as a specialty and may not have much experience with the practice, which could also be a barrier to referrals. Thus, educating clinicians about PC throughout medical training and beyond may help improve their use of PC services.⁴¹

Future Directions

Despite the barriers to the involvement of PC in the care of patients with advanced cancer, strong evidence now supports integrated palliative and oncology care. To successfully move this field further, one must consider (1) which aspects of the PC interventions led to the improvements in patient-reported and health care measures, (2) whether nonspecialized PC clinicians can be effective in providing this care, (3) which patients benefit most from the integrated care model, and (4) when in the course of disease should the integrated model begin.

First, essential components of the novel care model that led to the improvements in patient outcomes must be identified. Although each trial involved integrating an early PC model with usual oncology care, no intervention was entirely scripted or manualized, making it difficult to discern the key elements of the PC model. Thus, delineating more specifically how PC clinicians spend visits with patients may provide insight into the mechanisms of improvement. A retrospective qualitative study of patients from the Temel et al²² study identified 7 themes in PC notes, including relationship and rapport building, addressing symptoms, addressing coping, establishing illness understanding, discussing cancer treatments, EOL planning, and engaging family members, all of which may be integral to the improvements in outcomes seen with PC.⁴² These themes were present in varying degrees during a patient's illness. For example, early visits included more rapport building and illness understanding, whereas EOL planning was more often present in later visits. At times of progression on imaging studies or clinical deterioration, both oncology and PC addressed symptom management, illness understanding, and EOL care planning. However, oncology also focused on cancer treatment and managing medical complications, whereas PC focused more on coping and the psychological impact of the turning point, suggesting that the teams played complementary roles. Because PC visits incorporated more psychological support and coping, and these elements of care were less prominent in oncology visits, they may be important aspects of the mechanisms of benefit in the early integration of PC that require further investigation. Additionally, although some elements of oncology and PC visits overlap with regard to symptom management, illness understanding, and EOL care planning, the PC and oncology clinicians may have different approaches to these elements that are not fully captured in written notes. Thus, future studies of audiorecorded visits may provide better data to understand the benefit of PC integration and better delineate the differences between the care teams.

In addition, the role of early PC in enabling patients to develop prognostic understanding may be another important element to influence outcomes. In the study by Temel et al,⁴³ more patients receiving early PC retained or developed an accurate assessment of their prognosis over time. Additionally, patients receiving early PC were less likely to receive intravenous chemotherapy near EOL and had significantly longer hospice stays.⁴⁴ Thus, early integration of PC with oncology care influenced patients' prognostic understanding and decision-making, particularly as it related to the timing of transitioning from cancer-directed therapy to supportive care alone. Further research should define the role PC plays in the evolution of patients' prognostic awareness and medical decision-making to allow for future dissemination.

Once the specific practices of early integrated PC have been distilled, whether any of the identified elements of care can be incorporated into the practice of non-PC-specialized clinicians will need to be determined, because it will not be feasible for every patient with cancer to be seen by PC. As proof of principle studies, these trials entailed intensive interventions in which patients saw PC at least monthly throughout their illness. Disseminating such intensive models is not possible throughout the health care system, because there are currently not enough PC clinicians for every patient with advanced cancer to be seen so often, and such an intensive intervention would likely be too costly.⁴⁵ Thus, identifying whether some basic PC skills can be integrated into non-PC clinician practice

may allow more patients to benefit from a greater attention to their supportive care needs. Quill and Abernethy⁴⁶ proposed a model of primary and specialist PC, in which non-PC–specialized clinicians include more core elements of PC in their practice. These elements include basic symptom management and general discussions about prognosis, goals of care, and code status. In their model, the PC specialist would then only be involved for more complicated needs, such as uncontrolled symptoms, complex psychosocial needs, and conflict resolution regarding goals of treatment. As elements of early integrated PC are better defined, institutions can develop educational training programs to disseminate the elements of a PC skill set to other clinicians.

The 3 studies highlighted here included patients with a variety of poor-prognosis cancers who were predominantly married, white, and had at least a high school education. However, this narrow population is not representative of all patients with cancer, and other populations may not derive the same benefit and may require a different model of supportive care. For example, one retrospective study investigated the relationship between improvements in symptom burden and race and ethnicity in patients referred to PC. The study found disparities in symptom response among non-Hispanic whites, Hispanics, and non-Hispanic blacks.⁴⁷ Future research should explore further whether patients' sociodemographic variables impact the efficacy of an integrated care model.

Although the study by Temel et al⁴³ enrolled only patients with metastatic non–small cell lung cancer, the other studies included a variety of cancer diagnoses. Because improvements were seen in all 3 studies, patients with all types of cancer likely benefit from an integrated care model. However, the role that PC plays in the care of different cancer types likely varies dramatically. For example, in a population such as patients with metastatic breast cancer, which is an incurable malignancy with a varied prognosis, PC may focus more on helping patients cope with uncertainty, whereas for patients with metastatic pancreatic cancer, PC clinicians may focus more on managing physical symptoms and helping patients and families cope with frequent hospitalizations. Thus, future research should determine how PC can best support each cancer population based on the illness trajectory and care needs.

Not only should the focus of PC likely be individualized based on cancer types, but also the optimal timing for involving PC may differ based on a patient's prognosis and symptom burden. How long, how early, and how often PC should be involved remains unclear because all 3 studies included patients with poor prognoses, ranging from 6 to 24 months. For patients with a longer prognosis, such as those with epidermal growth factor receptor–mutated lung adenocarcinoma, which can have a life expectancy of many years, whether PC should be integrated over the entire disease course or whether there is an optimal turning point in the cancer trajectory at which PC should become involved is unknown. Encouraging clinicians to refer patients once they estimate the prognosis to be 1 year is one possible referral strategy. However, asking clinicians to use patients' prognosis to identify the optimal timing for involving PC is difficult because of clinicians' known optimism and the improvements in survival with advances in cancer therapeutics.^{48,49} Thus, identifying a reliable marker for clinicians to use to trigger PC integration in patient care is paramount to being able to integrate PC most beneficially and productively across the health system.

Possible markers could include disease progression after first-line therapy, hospitalization, or the development of an increased symptom burden.⁵⁰

Conclusions

Carefully conducted scientific research is not only driving advances in cancer biology and treatment, but also contributing to the development of innovative patient care models focused on providing the best care for patients and their families facing serious illness. As caring for patients with cancer becomes increasingly complex, the early integration model of PC into oncology care has shifted the paradigm of standard oncology care. The 3 highlighted studies demonstrate that early integration of PC improves QOL, depression, prognostic understanding, and health service use in patients with advanced cancer. These remarkable outcomes provide a critical foundation for continued early integration of PC into oncology care, although several unanswered questions remain. These questions include defining the mechanisms of improvement from the PC interventions, establishing who benefits from early integrated PC, and determining whether non-PC clinicians can integrate some beneficial aspects of PC into their practice, all of which lay the groundwork for future research in this field.

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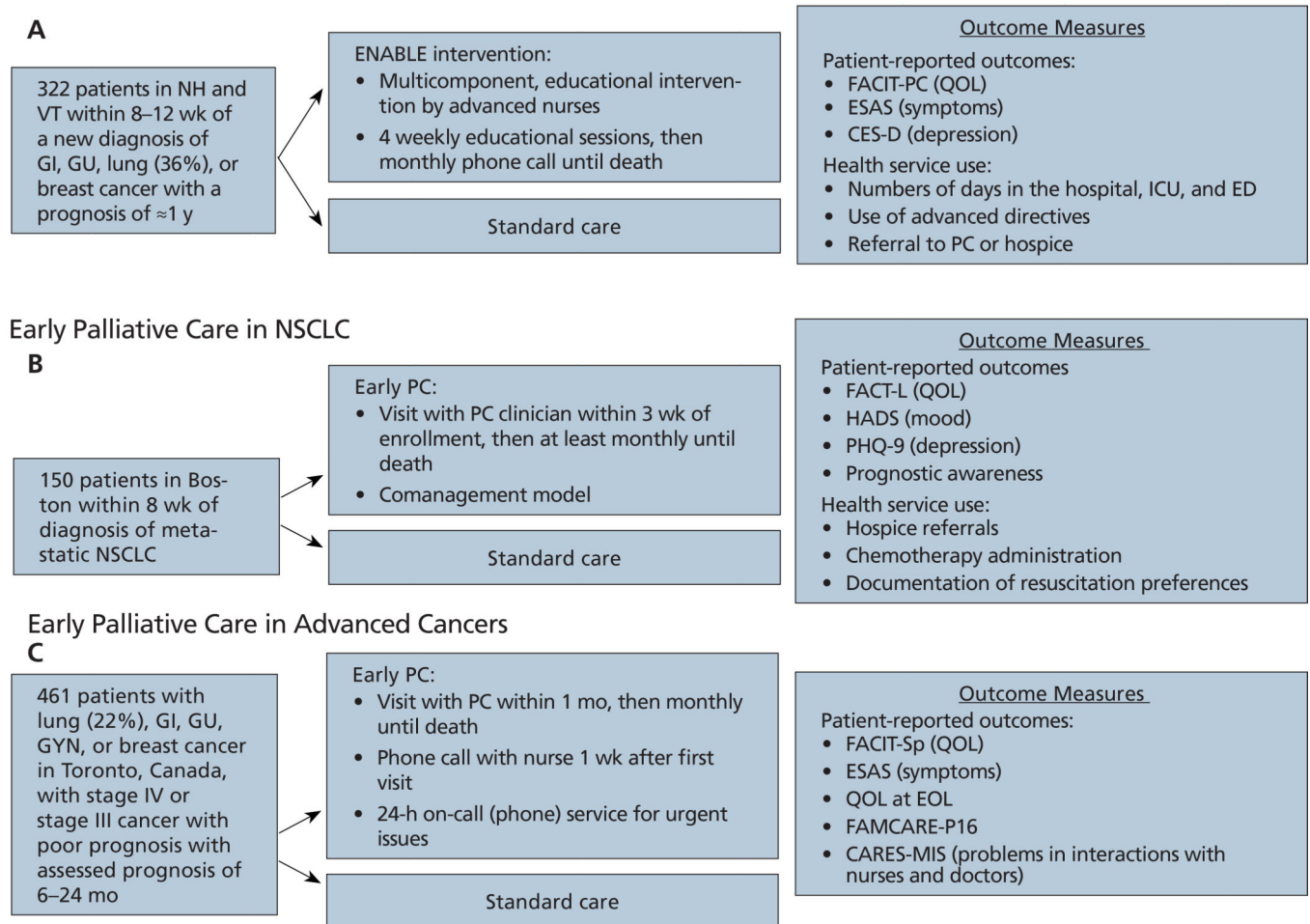
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Learning Objectives

Upon completion of this activity, participants will be able to:

- Describe the mechanisms through which early PC improves patient outcomes
- List the most common barriers to the integration of PC into cancer care
- Discuss the future directions of early PC models in oncology care

Project ENABLE II

**Figure 1.**

The trial designs: (A) Project ENABLE II,²¹ (B) early palliative care in NSCLC,²² and (C) early palliative care in advanced cancers.²³

Abbreviations: CARES-MIS, Cancer Rehabilitation Evaluation System Medical in Interaction Subscale; CES-D, Center for Epidemiological Studies Depression Scale; ED, emergency department; ENABLE, Educate, Nurture, Advise, Before Life Ends; EOL, end of life; ESAS, Edmonton Symptom Assessment Scale; FACT-L, Functional Assessment of Cancer Therapy-Lung; FACIT-PC, Functional Assessment of Chronic Illness Therapy-Palliative Care; FACITSp, Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being; FAMCARE-P16, FAMCARE Patient Satisfaction with Care 16-item measure; GI, gastrointestinal; GU, genitourinary; GYN, gynecologic; HADS, Hospital Anxiety and Depression Scale; ICU, intensive care unit; NH, New Hampshire; NSCLC, non-small cell lung cancer; PC, palliative care; PHQ-9, Patient Health Questionnaire 9; QOL, quality of life; VT, Vermont.

Table 1

Summary of Seminal Randomized Controlled Trials of Early Palliative Care Integration

Bakitas et al ²¹	<ul style="list-style-type: none"> Estimated treatment effect (intervention-usual care) of longitudinal data set showed change in FACIT-PC +4.6 ($P=.02$), ESAS -27.8 ($P=.06$), CES-D -1.8 ($P=.02$) No differences in days in the hospital, days in the ICU, or ED visits No differences in PC or hospice referrals <p><u>Conclusions:</u> ENABLE II showed improved QOL and mood, and a trend toward improved symptoms in the PC intervention group, but no difference in health service use</p>
Temel et al ²²	<ul style="list-style-type: none"> At 12 weeks, FACT-L scores were higher in the intervention group (98.0 vs 91.5; $P=.03$) and fewer patients had depressive symptoms per HADS (16% vs 38%; $P=.05$) and PHQ-9 (17% vs 4%; $P=.04$) More patients in intervention group retained or developed an accurate assessment of prognosis over time 43 (82.5% vs 59.6%; $P=.02$) Fewer patients in intervention group had aggressive care at EOL, defined as chemotherapy within 14 days of death, no hospice care, or admission to hospice 3 days before death (33% vs 54%; $P=.05$), and also had longer hospice stays (median, 11 vs 4 days; $P=.09$) Intervention group had longer survival (11.6 vs 8.9 mo; $P=.02$) <p><u>Conclusions:</u> Patients in the early PC arm experienced improvements in QOL and mood, received less aggressive care at EOL, and had improved prognostic understanding, longer hospice stays, and improved survival</p>
Zimmermann et al ²³	<ul style="list-style-type: none"> A trend was seen toward improvement in the difference of scores between intervention and control arms for FACIT-Sp at 3 mo (3.56; $P=.07$), which became significant at 4 mo (6.44; $P=.006$) Significant improvement was seen in the difference of scores for QUAL-E and FAMCARE-P16 between groups at 3 and 4 mo (2.25, $P=.05$ vs 3.51, $P=.003$; and 3.79, $P=.0003$ vs 6.00, $P<.0001$, respectively) No difference in scores was seen between groups for the ESAS at 3 mo (-1.70; $P=.33$), but a significant difference was seen at 4 mo (-4.41; $P=.05$) No difference in scores between groups was seen for the CARES-MIS Higher numbers of PC unit admissions (7.5% vs 0%), inpatient PC consultations (7.9% vs 0.9%), and PC home nursing (17.1% vs 3.0%) and home PC physician (7.9% vs 3.0%) referrals were seen in the intervention arm <p><u>Conclusions:</u> Patients assigned to early PC showed a trend toward improved QOL at 3 mo, which became significant at 4 mo, and improved satisfaction with care at both time points, and improved symptom burden at 4 mo</p>
Similarities	<ul style="list-style-type: none"> All 3 trials were randomized, although none were blinded All included QOL as the primary outcome measure Both studies of in-person PC models involved comanagement with monthly PC visits, whereas the Bakitas study used telephone-based educational modules with monthly calls
Differences	<ul style="list-style-type: none"> The Bakitas study was conducted in a rural setting The Bakitas study was more structured than the other interventions, with specific educational objectives and a manual for the telephone modules The Bakitas and Zimmermann studies included many types of advanced cancers, whereas the Temel study only included patients with non-small cell lung cancer The Temel and Zimmermann studies demonstrated differences in health service use Only the Temel study demonstrated a difference in prognostic understanding, although it was the only study to measure this aspect

Abbreviations: CARES-MIS, Cancer Rehabilitation Evaluation System Medical Interaction Subscale; CES-D, Center for Epidemiological Studies Depression Scale; ED, emergency department; ENABLE, Educate, Nurture, Advise, Before Life Ends; EOL, end of life; ESAS, Edmonton Symptom Assessment Scale; FACT-L, Functional Assessment of Cancer Therapy-Lung; FACIT-PC, Functional Assessment of Chronic Illness Therapy-Palliative Care; FACIT-Sp, Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being; FAMCARE-P16, FAMCARE Patient Satisfaction with Care 16-item measure; HADS, Hospital Anxiety and Depression Scale; ICU, intensive care unit; PC, palliative care; PHQ-9, Patient Health Questionnaire 9; QOL, quality of life; QUAL-E, Quality of Life at the End of Life.