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*CONSIDER PALLIATIVE CARE: A DECISION AID TO IMPROVE PALLIATIVE CARE
KNOWLEDGE*

A Thesis Presented to
The Faculty of the School of Medicine
Yale University

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Master of Medical Science

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Abstract

Palliative care enhances a patient's quality of life by managing symptoms and psychosocial needs and facilitating advanced care planning. Engagement with palliative care improves satisfaction with care in patients and the informal caregivers identified by patients. However, palliative care is underutilized because many patients and their informal caregivers have limited knowledge about palliative care. Decision aids effectively educate patients and informal caregivers in a variety of clinical settings. **We propose a randomized clinical trial that will test the effectiveness of a decision aid for informal caregivers considering palliative care.** Specifically, we will match informal caregivers to a decision aid and compare the efficacy of this aid to that of usual care. Improved informal caregivers' knowledge of palliative care may increase patient and informal caregiver engagement with its service. The decision aid may significantly increase learning compared to usual care, which will impact guidelines regarding the approach to palliative care referrals.

Chapter One: Introduction

1.1 Overview

Palliative care (PC) addresses the physical, psychosocial, and practical consequences of a serious illness. With coordinated care, it manages patients' symptoms and supports patients and informal caregiver needs.¹ There is a critical need to improve patient and informal caregiver PC education, as patients and informal caregivers continue to misunderstand and subsequently not use its service. Decision aids (PtDA) have effectively educated patients and informal caregivers about a variety of healthcare topics, and are well-suited to improve PC knowledge. Our study aims to design and evaluate the effectiveness of a PC PtDA for informal caregivers.

1.2 Palliative Care Benefits

There is robust evidence showing PC benefits patients, informal caregivers, and the healthcare system. In fact, the American Society of Clinical Oncology (ASCO) recommends PC for all advanced cancer patients and their informal caregivers.² PC increases patients' quality of life (QOL) through various mechanisms.³⁻⁵ Compared to usual care, those who use PC experience significant improvements in their physical, psychosocial, emotional, and functional well-being.^{6,7} PC also facilitates advance care planning (ACP), further enhancing patients' QOL.^{5, 8, 9} Patients engaged in ACP are more likely to receive preference-matched care and report greater satisfaction than those who do not use ACP.^{10, 11} Additionally, using PC and ACP helps patients accept a terminal diagnosis, reducing aggressive and futile therapies at the end of life (EOL).^{4, 8, 10, 12} PC also extends life expectancy. Temel, et al., found that newly diagnosed cancer patients who used early PC lived an average of 11.6 months, whereas the standard care group lived just 8.9 months (p=0.02).¹³

PC interventions also increase informal caregivers' QOL. PC sessions guiding caregivers or patient-caregiver dyads through QOL challenges significantly improved caregiver QOL across

burden, stress, spiritual, and physical well-being domains verses usual care.^{7, 14} PC also facilitates EOL conversations, which prepare caregivers for death and improve bereavement adjustment.¹² The effect of EOL conversations on patient care further impacts caregivers' QOL. Fewer QOL conversations have been linked with more aggressive care and reduced patient QOL, causing caregivers to feel more regret ($p=0.01$) and depression ($p=0.03$).¹² A caregiver's QOL is expected to decline as a patient's health worsens. One PC intervention slowed this decline and enabled caregivers to better maintain their QOL across the illness trajectory. Here, caregivers using PC experienced a rate of decline less than half the rate of those not using PC ($p=0.02$).¹⁵

PC conserves healthcare resources in part by clarifying prognoses, which reduces the use of aggressive, futile, and expensive treatments.¹⁸ Its service may reduce hospital and ICU admission rates and length-of-stays.^{12, 16} Across studies, hospitalized patients receiving a PC consultation within three days of their admission saved on average \$3,237.00 in direct hospital costs per patient compared to those who did not get a consultation.¹⁷

1.3 Knowledge, Perceptions, and Communication about Palliative Care

Despite its benefits, low utilization and poor understanding of PC persist among patients and informal caregivers. Only 40.5% of caregivers in one study¹⁹ and just 49.5% of patients in another²⁰ reported using this service. One systematic review revealed PC referral rates ranging between 0-38% for interstitial lung disease patients.²¹ Patients and informal caregivers commonly cited insufficient information about PC as a barrier to using its service.^{19, 20} In fact, barriers extend beyond the public's lack of awareness and include many misunderstandings about PC. Patients and informal caregivers often incorrectly link PC with death, EOL care, and the need to suspend life-prolonging treatment.²¹⁻²³ A 2019 survey with 3445 respondents found that both a lack of knowledge and misconceptions about PC remain highly prevalent. Here, 66% of respondents had never heard of PC. Only 13% felt they had enough knowledge to explain it to

someone else; however, only 51% of this group could correctly answer three questions meant to assess the accuracy of their perceived understanding.²⁴ Misunderstandings regarding PC present an important barrier to its use because they promote negative connotations and a fear of PC, leading to avoidant behavior and an unwillingness to engage with the service.²²

In outpatient settings, many patients and caregivers are initially introduced to PC by clinicians who are not specialized in PC, such as primary care providers or oncologists. These providers can deliver PC themselves or refer patients and their caregivers to PC specialist teams. It is recommended that providers discuss palliative care soon after a serious illness diagnosis. No guidelines dictate how clinicians should conduct these conversations, so the approach to them often depends on the provider's communication abilities and comfort with PC.^{1, 25, 26}

A clinician's presentation of information strongly affects a patient's treatment choice, at times more so than the treatment's actual performance.²⁷ Studies assessing barriers to PC use reveal that this is also the case with PC misunderstandings.^{22, 28} Patients and caregivers report that providers will often use phrases such as, "it's too early for PC", and imply that there is a dichotomy between curative therapy and PC.²² Moreover, educating patients about PC may enhance preference for its service.^{4, 29, 30} In one trial, patients educated about early PC benefits had less fear, an increased belief in its efficacy, and a greater intention to use its service than those who were not educated ($p < 0.001$).^{4, 13} It is apparent that an informed patient is more likely to engage with PC, underscoring the importance of education to increase utilization.

1.4 Decision Aids

PtDAs are education tools that support patients in the decision-making process and supplement patient-provider communication by standardizing information provision and conveying patients' values to providers. PtDAs commonly include an explicit statement of the impending decision and information about treatment options and relevant health outcomes.

While traditional education presents information in a generalized manner for all patients, PtDAs in contrast ask users to consider the congruence between the information and their personal values.³¹⁻³³ PtDAs are well-received by patients and informal caregivers. Users report that they comfortable with the tools, find them helpful, and would recommend them to others.³⁴ In one study, between 82.8 and 90% of patients used PtDAs provided to them.³⁵

Previous data suggests that PtDAs are well-suited to address low PC knowledge and use. In a large systematic review comparing PtDAs to usual care, PtDAs were found to increase patients' medical comprehension. All patients completed knowledge tests, and those who used a PtDA scored on average 13.27 points higher on a standardized 100-point scale than those who underwent usual care.³¹ Not only have PtDAs increased users' knowledge, but they may also induce behavioral changes. Compared to the use of an advanced directive alone, the PREPARE PtDA improved scores for most Behavioral Change and Action Subscales, including contemplation (effect size $d=0.7$), self-efficacy ($d=0.44$), and flexibility ($d=0.87$).³⁶ In ambulatory settings, communication tools were also associated with a 1.92-fold increase in DNR completion rates compared to usual care or less intensive tools.³⁷ Furthermore, PtDAs improve patient satisfaction with behaviors, which is frequently evaluated as a part of decisional conflict. Across 105 studies, the use of a PtDA reduced decisional conflict by an average of 7.22 points on a standardized 100-point scale compared to usual care.³¹ Due to the values-clarifying nature of PtDAs, they work well for decisions where individuals value advantages and disadvantages differently, and would appropriately accommodate the personal nature of PC.³¹

1.5 Informal Caregiver Impact on Decision-Making

In an effort to enhance PC knowledge and use, research has explored PC communication with patients with comparatively less focus on communication with informal caregivers.

However, caregivers may heavily influence treatment decisions. Laidsaar-Powell, et al. found

that there is rarely no family voice in a cancer treatment decision. Instead, family members often exert as much as influence as patients by either directly offering their own opinions or through proximal actions such as emotional and informational support.³⁸ Most patients may also prefer involving family in decision-making over making unilateral decisions.^{39, 40} In some instances, family members have an even greater influence on decisions as they often adopt the role of surrogate decision maker before the patient becomes incapacitated.⁴⁰ Caregivers of South Korean advanced cancer patients completed 40.3% of consent forms of which many involved EOL care decisions. PC helps to clarify EOL care preferences, so these caregivers could certainly benefit from its services.⁴¹ Furthermore, one study showed that caregiver preferences, not patient preferences, were significantly associated with PC use.¹⁹ Based on this evidence, it is worthwhile to focus more attention on improving communication with informal caregivers about PC.

1.6 Statement of the Problem

Studies demonstrate that PC benefits patients, caregivers, and the healthcare system. However, the service continues to be underused. It is critical to improve PC knowledge since a primary reason for a lack of participation is a lack of accurate understanding.¹⁹⁻²³ Furthermore, evidence suggests that improving PC knowledge is associated with an increased intention to use its service.⁴

There have been no trials investigating the efficacy of a PtDA for informal caregiver PC education thus far. There is strong evidence that PtDAs are a promising approach to improve PC knowledge. Since informal caregivers play an integral role in the decision to participate in PC, it is worthwhile to study novel ways to improve informal caregiver PC knowledge.

1.7 Goals and Objectives

The goal of this study is to determine the effect of a PtDA on informal caregivers' PC knowledge. We will present the PtDA to informal caregivers of advanced cancer patients

diagnosed within the past eight weeks. To demonstrate the PtDA's efficacy, the primary outcome will be the mean difference in improvement of PC knowledge from baseline to one month after the study between those who did and did not receive the PtDA.

Secondary outcomes include differences in PC knowledge improvement from baseline to immediately after the study, six months after the study, PC usage rates, decision quality, and emotional distress between those who did and did not receive the PtDA. Informal caregivers will also rate the PtDA's acceptability.

1.8 Hypothesis

We hypothesize that there will be a significant difference in PC knowledge improvement from baseline to one month after the study in informal caregivers using a PtDA verses usual care.

1.9 Definitions

Informal caregiver: an unpaid friend or family member who provides primary support to the patient

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Chapter Two: Systematic Review of the Literature

2.0 Summary Overview

In the following section, we review studies about PC education techniques, serious illness PtDAs, and informal caregivers' PC information needs. These studies provide background information for the development of our study, including establishing direction for future study and expanding on study design considerations.

2.1.0 Current Methods of Palliative Care Education

In order to find information about current efforts to educate patients and informal caregivers about PC, we undertook a systematic review of the literature from December 2019 to March 2020 using Ovid (Medline), APA PsychINFO, AMED, CINAHL, PubMed, and Cochrane Medical Library. To find studies, the following were used as MeSH terms and as free keywords independently and in combination: *palliative care, palliative medicine, patient education as topic, caregiver education, education, carer, caregiver*. We also searched references of included studies. We limited the review to articles published in English within the last ten years and to adult (18 years and older) patient or informal caregiver populations. We reviewed titles and abstracts to ensure relevance to the proposed study.

From this method, we identified ten papers. We included one additional study despite being older than the ten year range because it is the original study for a closely-related follow-up study that is published within the last ten years, bringing the total number of papers in this review to 11.^{1,2} Of these 11 papers, three are randomized control trials (RCT),³⁻⁵ three are pilot RCTs,⁶⁻⁸ three are mixed methods studies,⁹⁻¹¹ and two are prospective cohort studies.^{1,2}

A variety of techniques were used to educate study participants about PC, including: PC consultation with or without a PtDA,⁶ a group education session with or without an advanced care planning (ACP) handbook,¹⁰ meetings with a PC clinician,⁹ booklets with worksheets about

different aspects of cancer care,^{7,8} summary of results from the Early Palliative Care Study,³ a video about PC,^{4,5} and a community lecture about PC topics.^{1,2}

Many studies involved patients or patient-caregiver dyads as the participants^{3,5-7,9}. Three studied community laypersons.^{1,2,4} Two studied informal caregivers; however, one study provided information about PC specifically in a cancer care context,⁸ and the other did not objectively measure the intervention's impact on informal caregivers.¹¹ There remains a need to study general PC education and its objective impact on informal caregivers.

2.1.1 Impact on Palliative Care Knowledge

Seven studies examined the impact of various interventions on study participants' PC knowledge, with five papers^{3,7-10} finding improved levels of knowledge and two papers^{5,6} not. However, there are methodological discrepancies across studies that explain the varied conclusions on knowledge drawn in the following studies.

In a pilot RCT, Matlock, et al. found no significant difference between the use of a PC consultation with a PtDA versus a PC consultation alone on PC knowledge in informal caregivers or patients referred to the inpatient PC service.⁶ The control group received a PC consultation. The intervention group received a PC consultation along with a PtDA designed for patients facing serious or terminal illnesses. It introduced PC and ACP, and clarified goals and values. Prior to the study and then several days after undergoing either the control or intervention activities, participants took a six-question, true-or-false PC knowledge test developed by two of the study's authors. There was no significant change in pre- and post-test scores within each group, with the control group initially scoring 56% and increasing to 62% ($p=0.40$), and the intervention group increasing from an initial 72% to a 78% ($p=0.33$). There was also no significant difference in post-test scores between the groups ($p=0.35$). One explanation for these results is low enrollment, resulting in a study that was underpowered to detect small differences

in knowledge. Only 51 of the eligible 239 patients or informal caregivers enrolled, and many declined as decisions were already made. The lack of significant difference in post-test scores between each group may also be due to the control group receiving a PC consultation, where they were taught about the service. It is therefore difficult to determine if these nonsignificant findings for post-test scores were due to an ineffective PtDA, or to both groups receiving a form of PC education. Introducing the PtDA earlier in the treatment trajectory and not providing the control group formal PC education would address these potential issues in future trials.

Graul, et al. measured no significant changes in outcomes following the delivery of a PC video to 111 cancer patients in an RCT.⁵ The intervention group watched a PC educational video while the control group watched an unrelated video. Prior to watching the videos, 60% of the intervention group and 66% of the control group reported an awareness of PC, with no significant difference between each group ($p=0.51$). After watching the videos, patients assessed their PC knowledge with the PC Knowledge Scale (PaCKS) exam. Both groups achieved a median score of 12/13 questions correct with no significant difference between each group ($p=0.65$). Since a large portion of subjects had already heard of PC, additional education may not have been beneficial. This is likely to be an unusual population considering the poor performances in national surveys regarding PC understanding in laypersons.^{12, 13}

A quasi-experimental study by Sung, et al. evaluated the impact of group education with an ACP booklet compared to group education alone on PC knowledge and self-rated PC understanding in 57 residents of Taiwanese long-term care facilities, with positive results.¹⁰ Both the group education session and the ACP booklet conveyed information about PC and various ACP topics. Patients took a knowledge test before and after the study, which consisted of 21 questions paired with yes, no, and unsure answer options. There was no significant difference in

PC knowledge at baseline between the groups ($p=0.951$). After the intervention, both groups experienced significant improvements in knowledge scores ($p<0.001$). However, the experimental group had a significantly greater post-test knowledge levels than the control group ($p=0.014$), suggesting that the ACP booklet played an important role in patient education. Aspects of the study's methodology weaken its claim regarding the impact of the intervention on PC knowledge. Due to a Taiwanese cultural stigma regarding death, patients were assigned to each study arm based on their willingness to openly discuss ACP, resulting in a non-random allocation process. Also, patients reportedly underwent testing at baseline, immediately after, and six months after the intervention to study long-term knowledge levels. Yet only two sets of data appear in the paper with no specified timing of the post-test results, so it is not possible to prove that the intervention had a long-term impact. One methodological strength is including “unsure” as an answer, eliminating guessing as a confounding factor for test scores, which is an issue in other tests, such as the PaCKS exam and the Knowledge of Care Options (KOCO) test.

Schulman-Green, et al. evaluated booklets with worksheets and conversation starters promoting self-management and educating cancer patients and informal caregivers about cancer care topics, including care options.^{7,8} Evidence from two pilot studies showed that the intervention improved knowledge. For this review, we located only the abstract for the pilot RCT studying the intervention versus symptom management education on informal caregivers.⁸ The booklets had a medium effect size on informal caregiver knowledge of care options at one and three months. No further description of data measurement was provided. The other pilot study used a one-group pre- and post-test design to study the effect of the booklets on metastatic breast cancer patients.⁷ Participants took KOCO before and one month after receiving the booklets. At one month, there was a significant improvement in scores from baseline ($p=0.0056$). While the

results are promising, they are limited by the structure of KOCO. KOCO consists of 11 true-or-false questions about curative, hospice, and PC specifically within the context of cancer care. Using only true-or-false questions creates the possibility of guessing confounding test scores. Future studies should take steps to mitigate the effect of guessing on knowledge assessment results, such as including a confidence rating for answers or an unsure answer option. This study also uses no control group, so it is unclear if the method of information delivery is critical to improving knowledge versus simply providing information. An ongoing RCT evaluating the same topic does use a control group receiving standard symptom education.¹⁴

Harden, et al. performed a mixed methods study in which 25 patients undergoing hematopoietic stem cell transplantation (SCT) attended two PC meetings with or without an informal caregiver.⁹ The meetings improved self-perceived PC knowledge. Prior to the patients' admission, study subjects attended an educational meeting and received written materials about PC and related topics. The second meeting occurred seven to ten days post-admission and focused on addressing patient's needs. Subjects then reported self-perceived gains in PC knowledge 2 weeks post-discharge. After intervention, 83% of participants felt that their knowledge increased at least somewhat to very much and 92% felt they had enough information to access PC in the future. As there was no control group, the true impact of the intervention on knowledge is unclear. While it is promising that participants found the PC meetings educational, self-perceived PC knowledge may correlate poorly with actual PC knowledge.¹³ Objective measures are needed to clarify this intervention's impact on PC knowledge.

Kozlov, et al. assessed the impact of either a PC information page or video versus a control information page or video in an RCT involving 152 community members.⁴ PC knowledge significantly improved in the intervention groups compared to the controls. The

intervention video depicted a physician discussing PC and contained accompanying text. The information page covered the same information as the video. The control video and information page were about an unrelated topic. To assess knowledge, patients took the PaCKS test, consisting of 13 true-or-false PC questions, before and after receiving the study materials. Patients also reported their confidence in answering each PaCKS question with a 5-point Likert Scale to account for the confounding effect of guessing on PaCKS scores. Scores significantly increased in the intervention groups compared to the controls ($p=0.00$). The effect size was small (0.076), but the clinically significant effect size for this outcome is unknown. PaCKS scores did not significantly change between the PC video or information page ($p=0.92$). Confidence in knowledge also significantly increased in the intervention groups versus the control groups with a medium effect size ($p=0.00$, $d=0.45$). The increased PaCKS and confidence scores offer convincing evidence that the interventions significantly impacted PC knowledge. When the post-test occurred was not specified, so it is not possible to know if the video or information page enacted a lasting, long-term effect on knowledge. After this study, Kozlov, et al. developed a PaCKS exam incorporating an unsure answer, which we will refer to as PaCKS 2.0.¹²

No method studied thus far has offered the ideal way to educate patients and informal caregivers about PC, and there is a need for further research to continue improving PC education. Study methodologies, frequently involving knowledge evaluations and a lack of adequate controls, weaken claims made about the impact of different techniques on knowledge. Future PC education research must consider these issues. There also remains an absence of strong evidence for the long-term impact of these interventions. Retention of PC knowledge is necessary for populations with long durations of illness given the potential need to use PC long after education.

2.1.2 Impact on Palliative Care Attitudes and Behavior

Five studies also investigated the impact of different education methods on PC attitudes and behaviors.^{1-3, 5, 10} Three studies reported positive results,^{2, 3, 10} while two reported negative results.^{1, 5} As with knowledge, a diverse set of approaches to measure and describe outcomes lead to varied conclusions on the impact of education on attitudes and behavior.

The RCT by Graul, et al. that tested the impact of a PC video on cancer patients' knowledge also evaluated their behaviors towards the service, with no significant changes measured.⁵ After completing the knowledge exam, patients were asked if they would like a referral for PC. Six months later, EMR records were searched to determine if patients attended a PC appointment. Twenty-seven percent of the intervention group versus 29% of the control group requested a referral ($p=0.79$), and 27% of the intervention group versus 36% of the control group attended an appointment ($p=0.79$). The trial required 124 patients to detect a 20% difference in PC use, but only 111 patients enrolled, and recruitment halted early, so it was underpowered to detect smaller changes in behavior. Approximately half of screened patients were excluded due to stringent exclusion criteria. Criteria based on the patient's chemotherapy regimen or treatment type were considered, but may be unwarranted as PC is meant for all patients regardless of their treatments. To mitigate the difficulty in recruitment, future studies should not include treatment types as exclusion criteria.

Graul, et al. also compared rates of PC use between all of the patients enrolled in the study and patients seen at the same clinic the previous year.⁵ There was a significant increase in PC use among both study groups compared to institutional rates from the year prior ($p<0.001$). Given that both groups were asked if they would like a referral as part of the trial, it may be that simple discussion alone, such as this question, is sufficient to increase interest in PC. There was no further investigation into this increase, so the cause of this behavior change remains unclear.

In two prospective cohort studies, Sato, et al. evaluated the short and long-term impact of a one-hour PC lecture delivered to the general public in Japan, with mixed findings.^{1,2} Before, immediately after, and six months after the lecture, 424 lecture attendees reported their attitudes towards several PC topics, such as feasibility of home-death, barriers to EOL home care, attitudes about EOL care, and preferences for life-prolonging treatment. There was a significant improvement in the majority of attitudes immediately after the lecture. However, this effect diminished over time, suggesting that the lecture failed to impart a long-lasting effect on attitudes. For instance, despite an initial increase from 10% before the lecture to 37% afterwards, the proportion of respondents at six months who believed home-death was feasible fell to 12%, representing a nonsignificant increase from baseline ($p=0.12$). Further, immediately after the lecture, significantly fewer participants considered eight out of ten items as barriers to EOL home care compared to before the lecture. At six months, the outlook on just one potential barrier was significantly different ($p=0.05$). To explore attitudes about EOL care, participants agreed or disagreed with 16 statements about this topic. With the exception of one statement, there was a significant difference in agreement or disagreement rates for all statements in the pre-test versus the immediate post-test. Between the pre-test and six-month post-test, there continued to be significant differences for seven statements, albeit five were improved to a lesser extent, and there was no significant difference for the remaining nine statements. Finally, attendees reported their preference for receiving different life-prolonging treatments. There were no trends for the proportions of respondents who preferred each treatment. Compared to before the lecture, there was a significant decrease in preference for some treatments at the immediate post-test, but not at the six-month follow up. Other treatments experienced significant decreases in preference at six months, but not at the immediate post-test.

Hoerger, et al. conducted an RCT to determine if providing patients with a summary of results from the Early Palliative Care Study, including effects on QOL, depression, and survival in patients, would impact their short-term preferences for PC and intentions to enroll in its service.^{3, 15} Researchers recruited 598 patients with heterogeneous cancer diagnoses to either receive the summary or no education. Patients completed surveys at baseline and immediately after the study about their PC preferences. Compared to the controls, patients who received the educational summary had a greater preference for PC ($d=1.01$, $p<0.001$), found PC to be more effective ($d=0.79$, $p<0.001$), and found it to be less scary ($d=0.60$, $p<0.001$). The intervention group also exhibited stronger behavioral intentions to use PC versus the control group and were more willing to attend a PC appointment if their physician recommended it ($d=0.60$, $p<0.001$). One particular strength of this study was the authors' use of analysis of covariance to study the impact of the summary across different cancer diagnoses, education levels, and financial strain. Not only did this adequately address confounding variables that would accompany the study's broad inclusion criteria, but the comparable effect sizes found between these groups demonstrate that the intervention could be similarly beneficial for a variety of people.

In a previously described quasi-experimental study, Sung, et al. evaluated how group education with or without an ACP booklet impacted long-term care facility residents' preferences for PC.¹⁰ At baseline and after the intervention, patients reported their willingness to use PC and their agreement with statements about PC benefits and barriers. At baseline, there was no significant difference between groups regarding attitudes towards and willingness to use PC. Afterwards, the intervention group had a significantly more positive attitude towards PC and were more willing to use PC ($p=0.016$) relative to the control group. The intervention's long-term efficacy is unclear as it is not known when the post-test data was collected.

Overall, previous PC education approaches had a mixed impact on PC attitudes and behaviors. Of the trials with negative results, issues with study methodology may have caused the nonsignificant outcomes. Graul, et al. had low recruitment and therefore too small of a sample to detect attitude differences between the study arms.⁵ In their surveys, Sato, et al. included barriers to EOL care that reflected living situations more so than the PC misconceptions their lecture was designed to address, thus skewing the results.^{1,2} There also remains little understanding of the long-term impact of educational techniques on PC attitudes and behaviors, since only one reviewed study evaluated this outcome.¹ However, it is critical to demonstrate the long-term efficacy of these interventions given that PC is administered at any point throughout a disease process and may be accessed long after initial education. As such, future research should evaluate the long-term changes in study populations.

2.1.3 The Demand for Earlier Education

As part of the evaluation of education techniques in several studies, patients and informal caregivers provided feedback on the manner in which information was provided.^{6,7,9} Common feedback included that the information was useful and that providing it earlier in the treatment trajectory would be overall more beneficial and have a greater impact on learning. For example, cancer patients who used educational booklets meant to promote self-management behaviors stated that they felt the booklets would most benefit patients who were newly diagnosed with cancer.⁷ Subjects who used a PtDA for serious illnesses also reported that the tool would have been most useful if it had been provided earlier in the disease course. Some participants advocated for the tool to be provided at or before the time of diagnosis, so that patients and their families could enjoy its educational benefits while making the majority of their care decisions.⁶ Currently, the tool was delivered too late in the treatment trajectory, and most decisions had already been made. As part of their study investigating the effects of two PC meetings on

patients' perceived PC knowledge, Harden, et al. interviewed PC nurse practitioners (NPs) to gain their perspective on the learning process.⁹ The NPs felt the intervention was useful and recommended that the initial appointment be scheduled as early as possible, including at the first mention of a transplant, in order to capture additional patients that do not make it to the SCT stage of treatment. They also noted that patients were very stressed at the time of the first PC meeting since they were preparing for a major procedure. Earlier PC education would permit patients to learn in a less stressful environment, thereby enabling them to learn more effectively.

There is a demand to deliver PC education early for patients and their informal caregivers. Not only have study participants consistently provided this feedback, but ASCO guidelines also recommend that PC be delivered early in the disease course.¹⁶ Despite this need, only two trials assessed early PC education for patients and informal caregivers.^{9, 11} In one of the studies, participants stated that they would like the education to occur even earlier.⁹ The other study by Bakitas, et al. assessed a booklet and video educating diagnosed cancer patients and informal caregivers about care options and ACP.¹¹ However, outcomes were limited to evaluating the feasibility of providing this education, so there is no evidence of its impact on users. These patients and informal caregivers had also already been using PC for some weeks. There remains a need to evaluate education introducing PC to newly diagnosed patients and families. Other trials using patients, all of whom had cancer, and informal caregivers as the study population had patients whose times since diagnosis measured in years, with Schulman-Green, et al. reporting an average of 8.3 years (2-40 years),^{7, 8} Hoerger, et al. reporting a median of 4 years (1.5 – 7 years),³ and Graul, et al. reporting an average of 2.95 years (1.5-5.6 years).⁵ Given the lack of research addressing this issue, there is a critical need for future studies to evaluate the delivery of early PC education and measure outcomes regarding to its impact on users.

2.1.4 Conclusion to Current Methods of Palliative Care Education

Among 11 PC education papers published within the last ten years, outcomes related to knowledge, attitudes, and behaviors were most frequently discussed. It is clear that these outcomes need further research with more strenuous methodologies. Future studies should focus on adequate enrollment and using a control group that does not receive a formal form of PC education to isolate the intervention's effect. Discussion surrounding measurement of PC knowledge highlights the need to use a scale that minimizes guessing as a confounder and to evaluate for long-term impact. Additionally, feedback from participants supports the introduction of PC early in the disease process.

2.2.0 Decision Aids in Serious Illnesses

In order to examine the role of PtDAs for informal caregivers in the setting of a serious illness, we undertook a systematic review of the literature from December 2019 to March 2020 using Ovid (Medline), APA PsychINFO, AMED, CINAHL, PubMed, and Cochrane Medical Library. To find studies, the following were used as MeSH terms and as free keywords independently and in combination: *decision aid, decision support techniques, decision support systems, carer, caregiver, family, family member*. We also searched references of included studies. We limited the review to articles published in English within the last ten years and to adult populations. We reviewed titles and abstracts to ensure relevance to the proposed study.

Fourteen articles were identified through this method. We excluded two papers as they reported only qualitative feedback on the PtDA's acceptability as a part of its development.^{11, 17} Of the 12 remaining articles, four are RCTs,¹⁸⁻²¹ four are pilot RCTs,^{6, 8, 22, 23} three are secondary analyses of included RCTs,²⁴⁻²⁶ and one is a pretest-posttest study.²⁷ We also referenced a Cochrane Review on PtDAs versus usual care since it was consistently cited in articles and provided an evidential basis for many outcomes.²⁸

Although we imposed no restrictions for the clinical setting, all of the papers investigated PtDAs designed for decisions made in the setting of a serious illness, including cancer,^{6, 8, 18, 26} advanced dementia,^{22, 27} heart failure,^{21, 23} or other nonspecific serious illnesses.^{19, 20, 24, 25} Of the 12 papers, eight involved patient-caregiver dyads^{6, 18, 19, 23, 24, 26} and six involved informal caregivers alone^{8, 20-22, 25, 27} as the study population.

2.2.1 The Impact on Decision-Making Quality

The impact of the PtDA on the quality of the decision-making process was evaluated for in eight of the 12 studies.^{6, 8, 18, 20-23, 27} Five of these papers found that the PtDA had a significant impact on the decision-making process,^{8, 18, 22, 23, 27} two did not find a significant impact,^{6, 21} and one found mixed results.²⁰ A variety of measures were used to assess decision quality, such as knowledge, decisional conflict, and congruence between participants' values and treatments. The differing results along with the various outcome measures underscore the complexity of the decision-making process and affect the lessons learned from these studies.

In a previously described pilot RCT, Matlock, et al. found no significant difference in decision quality between those who received a PC consultation with a PtDA and those who received a PC consultation only.⁶ To evaluate the quality of their EOL care decisions, patients and informal caregivers completed a shortened version of the Decisional Conflict Scale (DCS) before and several days after the study. While the group that received the PtDA and a PC consultation experienced a decline in decisional conflict, their post-test scores were not significantly lower than their pre-test scores ($p=0.09$) or the post-test scores of the group that received only a PC consultation ($p=0.41$). However, study subjects also provided feedback indicating that the PtDA did in fact affirm their decisions and reduce decisional conflict. One informal caregiver stated that if she had access to the PtDA during the patient's treatment course, "[she] would feel reinforced that [she] was going along the right path ... and did [her] best".

Perhaps the objective measures were nonsignificant because of low enrollment, rendering the study underpowered to detect a significant difference in DCS scores.

Yun, et al. found that a PtDA had a mixed impact on the decision quality in informal caregivers considering disclosing a terminal diagnosis to a family member with advanced cancer.²⁰ In this RCT, the intervention arm used a workbook and video PtDA educating informal caregivers about discussing terminal disease statuses with family. The control arm received a workbook and video about controlling cancer pain. Subjects completed DCS surveys before and after the study (one, three, and six months after). The DCS tool assesses for decisional conflict with six subscales. Lower scores indicate less decisional conflict, thus a better-quality decision. While using the PtDA significantly reduced overall decisional conflict compared to the control at one-month ($p=0.008$), only conflict ($p=0.003$) and values clarity ($p=0.007$) DCS subscales were significantly lower. Further, the PtDA's impact on decision quality diminished over time. Compared to the control at six months, using the PtDA significantly lowered only uncertainty ($p=0.014$) and values clarity ($p=0.039$) DCS subscales. In fact, the total DCS score ($p=0.040$) was significantly higher, indicating that the PtDA did not fully address informal caregivers' decision-support needs. Inadequate enrollment paired with a high attrition rate of subjects, primarily due to the family member's death, explain the nonsignificant difference in various DCS subscales between study arms. The study design required 444 enrolled subjects at one month. However, enrollment stopped after reaching 444 subjects at baseline. When 136 people then dropped out, the study had too few subjects to be adequately powered to detect DCS score changes. To avoid this issue in the future, studies involving serious illness populations should use enrollment goals that accommodate high attrition rates.

Yun, et al. also compared DCS scores at one month between informal caregivers whose patient knew their prognosis and caregivers whose patient did not.²⁰ This distinction may represent two types of informal caregivers: those who have and those who have not yet reached the action stage of the transtheoretical model of behavior. The PtDA had a greater impact on decision quality for informal caregivers whose patient did not know their prognosis, with significantly improved conflict ($p=0.009$) and values clarity ($p=0.003$) scores, than those whose patient knew their prognosis, with no significantly changed DCS scores. The varied impact of the PtDA on different informal caregiver populations suggests that not all caregivers have the same decision-support needs. To broaden the reach of future PtDAs, there is a need to consider these differences during PtDA development.

In a pilot RCT, McIlvennan, et al. found that a decision support program had a promising impact on the decision quality of patient-caregiver dyads considering destination therapy left ventricular assist devices (DT LVAD).²³ The program consisted of a decision support session with a DT LVAD PtDA for patient-caregiver dyads. Clinicians were also coached on discussing the PtDA materials. Investigators recruited ten patients and nine informal caregivers, 100% and 90% of the eligible participants respectively, with no follow-up losses. Their success may be attributed to ensuring clinical staff were aware of the trial through emails, fliers, and meetings. Staff were consequently likely to recruit subjects and correctly follow the trial protocol. Given the success, future studies studying a serious illness population should also consider a similar approach to overcoming low enrollment and high attrition rates. Since a high-quality decision matches a knowledgeable patient's or informal caregiver's values, investigators measured the change in subjects' knowledge from baseline to one month after the study, and the congruence between values and stated treatment preferences at one month. After using the PtDA, patients

and informal caregivers achieved higher scores on a DT LVAD test. Their values and stated treatment choice also matched. The significance of these findings is unknown since the study did not include a control group or report P values; however, a follow-up RCT addressed both of these issues.²¹

McIlvennan, et al. then compared how the DT LVAD PtDA and training sessions versus historically used DT LVAD education materials impacted decision quality in 182 informal caregivers in a stepped-wedge RCT across six clinics, with mixed results.²¹ Decision quality was based on participants' DCS scores, knowledge, and values-treatment congruence. Participants completed DCS and knowledge assessments before, immediately after, one month after, and six months after the study. All follow-up DCS scores improved from baseline within each group, but the control group experienced less decisional conflict than the PtDA group in the immediate ($p=0.007$) and six-month follow-ups ($p=0.078$). The PtDA may have incited greater decisional conflict because it more explicitly presented the risks and complexity of the decision than the control materials. All follow-up knowledge scores improved from baseline within each group with no significant difference between study arms. Informal caregivers who used the PtDA had a stronger correlation between their values and stated treatment preferences at one month ($p=0.03$) than the control. However, there was no significant difference between study arms for correlations between caregiver values and the patient's actual treatment at six months. ($p=0.08$). Study design weaknesses may be responsible for the nonsignificant knowledge and values-treatment congruence results. The six clinics implemented the PtDA in different ways and only 89.7% of subjects viewed the PtDA, which may have confounded results. A too-small sample size may have caused the nonsignificant knowledge results since, in an RCT assessing this intervention in a larger group of patients, a similar effect size seen in knowledge scores was

deemed significant.²⁹ The smaller informal caregiver population is likely because their recruitment was limited to enrolled patients, and these populations may not have the same availability. To mitigate this issue, future trials studying informal caregivers should plan for this difference during recruitment.

In a pilot RCT, Lord, et al. found that a PtDA improved decision quality in 41 informal caregivers of dementia patients deciding where the patient should be cared for in the future.²² Informal caregivers either completed a PtDA designed to reduce decisional conflict when choosing a place of care with a decision coach or received an Alzheimer's Society factsheet. After ten weeks, those who used the decision coach and PtDA experienced improved decision quality relative to those who did not, with respective DCS scores of 24.72 and 36.68 ($p=0.005$). The different DCS scores are also likely clinically significant because scores under 25 points are associated with making and implementing decisions. There were no significant differences in decisional conflict between groups at baseline, strengthening the evidence in support of the PtDA and decision coach. However, since the intervention group used both the decision coach and PtDA, the true impact of the PtDA is unclear. Further study is needed to isolate its effect.

Given that a high-quality decision is one that is an informed decision, Einterz, et al. measured knowledge to study how a PtDA affected decision quality in 18 informal caregivers of dementia patients, with positive results.²⁷ Caregivers used a PtDA meant to prepare them for a meeting with patients' care teams that would occur in three months. The PtDA shared information about advanced dementia and the role of the surrogate decision-maker, presented treatment options that aligned with different treatment goals, and contained a guide for informal caregivers to take the meeting. Informal caregivers took a knowledge test comprised of 18 true-or-false questions about dementia, goals of care, and treatment options. Their scores significantly

improved from baseline to three months ($p < 0.001$). While the results are promising, this PtDA requires more strenuous testing to be assured of its impact. The study is highly susceptible to bias since it does not use a control group and the true-or-false format of the knowledge exam is subject to guessing as a confounder. The study population was also small, homogenous, and well-educated, so there remains a need to assess the PtDA's efficacy in a broader population.

In two trials, Schulman-Green, et al. and El-Jawahri, et al. also measured knowledge to assess for decision quality, with promising results.^{8, 18} We only located the trials' abstracts for this systematic review. As described in Section 2.1.1, Schulman-Green, et al. provided 35 informal caregivers of advanced cancer patients either booklets with worksheets and conversations starters about cancer or symptom management education.⁸ There was a medium effect size for improved care option knowledge in the intervention group at one and three months. El-Jawahri, et al. conducted an RCT evaluating hospice education for patient-caregiver dyads where the patient was hospitalized for advanced cancer complications.¹⁸ Study subjects received a verbal description and video PtDA about hospice or the verbal description alone. Dyads who received the verbal description and video PtDA were significantly more knowledgeable about hospice than those in the control group ($p = 0.024$ for patients, $p < 0.001$ for informal caregivers) after adjusting for baseline knowledge levels. The imbalance between the number of enrolled patients, 150, and the number of enrolled informal caregivers, 44, reiterates the need to account for differences in patient and informal caregiver availability during recruitment in future trials studying informal caregivers.

Overall, evidence across the majority of studies suggest that PtDAs improve decision quality in informal caregivers of patients with a serious illness.^{8, 18, 22, 23, 27} However, there is a critical need to improve recruitment techniques in future trials studying serious illness

populations in order to address poor recruitment rendering studies underpowered and to allow for the incorporation of more diverse and larger study populations. In our review, the three trials with mixed or nonsignificant results experienced low enrollment or high attrition rates.^{6, 20, 21} Many reviewed studies also used small, homogenous populations, limiting the generalizability of supporting evidence for the PtDA. One reviewed study overcame enrollment issues by frequently communicating with clinical staff in an effort to capture every potentially eligible subject.²³ While there are several methods to detect decision quality, the DCS tool, knowledge, and values-treatment concordance were commonly used in these studies. These measures were also used in the trials evaluated by the Cochrane Review comparing PtDAs to usual care.²⁸ Here, PtDAs improved study participants' knowledge by an average of 13.27 points on a 100-point standardized scale across 52 studies. PtDAs also lowered DCS scores by an average of 9.28 points in 27 studies. Values-treatment concordance improved as well in ten studies.

2.2.2 The Behavioral Impact of Decision Aids

Seven studies also evaluated how the PtDA influenced the behavior of patients and informal caregivers.^{8, 18-20, 24, 26, 27} A broad range of outcomes were included, such as treatment preferences and the quality or frequency of communication between the patient-caregiver dyad and the clinical team. Four of the seven studies found that the PtDA significantly impacted behavior,^{8, 19, 24, 27} and three of the seven found nonsignificant or mixed results regarding the PtDA's behavioral influence.^{18, 20, 26} While there are promising findings, methodology frequently limits available evidence regarding PtDAs' impact on behavior.

In addition to decision quality, Yun, et al. assessed if a PtDA influenced informal caregivers' decision to disclose a terminal disease status to a family member with advanced cancer, and found that the PtDA did not affect their actions.²⁰ Informal caregivers reported whether or not they had disclosed the terminal prognosis to patients one month after receiving

either the PtDA meant to help them approach the disclosure process or the control materials. Forty informal caregivers who received the PtDA versus 45 in the control chose to disclose this information ($p=0.37$). As with decision quality, high attrition rates for study subjects likely rendered the study underpowered to detect a significant difference in this outcome. However, given that the PtDA also increased decisional conflict at six months, an insufficiently designed PtDA that did not fully support the informal caregivers' needs cannot be ruled out.

El-Jawahri, et al. measured patient and informal caregiver preference for hospice immediately after receiving descriptions of hospice care in a previously described RCT, with mixed findings.¹⁸ There was no significant difference in the proportion of patients who preferred hospice between study arms ($p=0.08$). The PtDA may not have adequately addressed patients' concerns about hospice, underscoring the importance of evaluating a populations' information needs during PtDA development. However, a significantly greater proportion of informal caregivers who received both the verbal description and video PtDA preferred hospice compared to those who received only a verbal description ($p=0.031$). While the informal caregivers' results are promising, preference for hospice care was only measured immediately after receiving the study materials. With no data collected prior to the study, it is unknown if there was a significant baseline difference between study arms, weakening evidence in support of the PtDA. There also remains a need to evaluate the long-term impact of the PtDA on behavior.

Song, et al. found that a PtDA had a mixed impact on prostate cancer patients' and informal caregivers' communication behaviors.²⁶ This paper is a secondary analysis of an RCT testing a PtDA with patient-caregiver dyads that we excluded from this review because it did not measure any informal caregiver outcomes.³⁰ The PtDA educated users about effective clinical communication and treatment options. Either only patients used the PtDA, both patients and

caregivers used the PtDA, or patients and caregivers used usual care. Their information-giving and question-asking patterns during office visits, which correlate with communication quality, were then observed. When only patients used the PtDA, communication during office visits significantly improved. Dyads provided more information, such as sharing information about symptoms ($p < 0.01$), and asked more questions, such as about treatment complications ($p < 0.05$), relative to the other study arms. Patient-caregivers dyads who both used the PtDA may have shown fewer information-seeking and question-asking behaviors because, with both receiving communication education, they could subsequently have higher quality conversations together outside the clinic to work through concerns. They would then need less information during office visits. However, without research elaborating on their behaviors outside the clinic, it is not possible to prove this concept. Very few informal caregivers attended the office visit, so investigators analyzed patient and informal caregiver communication patterns as one unit. Given the evidence demonstrating that PtDAs exert varied levels of influence on different populations, analyzing patients and informal caregivers as one unit may have limited insights into the nuances of the PtDA's performance. Future study designs should ensure greater caregiver enrollment to enable individual analysis of patients and informal caregivers.

In an RCT with a secondary analysis paper, Green, et al. examined how an ACP PtDA along with working alone or together affected treatment preferences in 267 patient-caregiver dyads facing a serious illness, and measured positive results.^{19, 24} Patients and informal caregivers either received the ACP PtDA or an advanced directive brochure. They then worked through the materials together or individually. Three to five weeks later, patients and their informal caregivers viewed clinical vignettes exploring various EOL medical treatments and reported their treatment preferences. Those who used the ACP PtDA were significantly more

likely to prefer less aggressive treatment than those who did not, with the PtDA group choosing a median of only one of the 11 presented aggressive EOL treatments and the brochure group choosing a median of five ($p < 0.001$). Further, patient and informal caregiver EOL treatment preferences aligned to a significantly greater extent in dyads who used the ACP PtDA than in dyads who used the brochure ($p = 0.032$). Whether the patient and the informal caregiver worked alone or together did not have a significant impact on the congruence of their treatment preferences ($p = 0.142$). The nonsignificant difference may have been due to patients and informal caregivers discussing the ACP PtDA and forming a consensus on treatment options outside of the research procedures. A particular strength of this study's design is its approach to recruitment. While the study required only 200 patient-caregiver dyads, investigators initially enrolled 285 dyads to compensate for the high attrition rates frequently occurring in this population and ensure there would be enough remaining subjects to adequately power the study.

Einterz, et al. found that a PtDA positively impacted communication quality between 18 informal caregivers of dementia patients and nursing home clinicians in a previously described RCT.²⁷ In preparation for a future meeting between caregivers and nursing home clinicians, informal caregivers used a PtDA about dementia and decision-making, and clinicians received communication coaching. Overall, communication quality significantly improved from baseline to the time of the meeting (three months). Informal caregivers scored their perception of communication quality, and scores significantly improved from baseline to three months ($p = 0.01$). Informal caregivers and clinicians were also in significantly greater agreement with each other about the care plan at three months relative to baseline ($p = 0.003$), reflecting a successful conversation about goals of care during their meeting. However, the communication

training received by the clinicians is a potential confounding variable. Further testing accounting for this variable is required to discern the true impact of the PtDA on communication quality.

Frequency of communication was also used to assess the behavioral impact of PtDAs. As part of the evaluation of booklets for informal caregivers of cancer patients, Schulman-Green, et al. noted that informal caregivers who received the intervention more frequently had goals of care conversations with a nurse than those who received the control.⁸ More frequent conversations indicated that the intervention group was engaging in more self-management behaviors. With only the abstract located for this review, the quality of this finding is unknown.

Seven studies investigated how PtDAs influence informal caregiver behavior using a variety of measures, commonly treatment preferences and communication. Four of these studies found positive results, establishing evidence that PtDAs can significantly influence behavior.^{8, 19, 24, 27} The Cochrane Review comparing PtDAs to usual care also measured similar results. PtDAs reduced the risk of clinician-controlled decision-making, meaning that patients and informal caregivers played a more active role in this area (relative risk 0.68, 95% confidence interval 0.55-0.83).²⁸ Other reviewed studies either found mixed or negative results, which often may be due to methodology errors such as high attrition rates or the confounding impact of patient and caregiver conversations outside of the study.^{18, 20, 26} In order to better discern the behavioral impact of PtDAs, there is a critical need for future study designs that will enable more rigorous testing of PtDAs to occur. For instance, future studies should recruit to accommodate high attrition rates, include control groups, and limit other interventions occurring in the same study.

2.2.3 The Emotional Impact of Decision Aids

Users' anxiety and depression are outcomes of interest in the study of PtDAs, particularly in populations facing a serious illness. PtDAs nudge people who may be in denial and fear to explicitly learn about risks of different choices and address life-threatening situations, increasing

their risk of becoming anxious and depressed.²¹ In our review, PtDAs had a mixed impact on informal caregiver's anxiety and depression.^{20, 22, 25} Contrary to the anticipated emotional impact of PtDAs, using a PtDA about dementia care did not cause informal caregivers to experience significantly different anxiety ($p=0.987$) or depression ($p=0.750$) levels compared to using usual care.²² After using control materials or a PtDA about disclosing terminal prognoses, informal caregivers reported results for their anxiety and depression levels that further support PtDAs.²⁰ The PtDA group had significantly lower depression levels than the control group at one ($p=0.007$) and six ($p=0.008$) months. There was no significant difference in anxiety levels between groups ($p=0.185$). However, the control materials had a comforting tone, thus they may have reduced anxiety in the control group and confounded the results. Therefore, it is unclear if the PtDA had no effect on anxiety or if it alleviated this emotion like it did for depression.

Informal caregiver characteristics may affect the emotional impact of a PtDA. In a secondary analysis of an RCT assessing a PtDA for informal caregivers considering disclosing a terminal prognosis, Yoo, et al. evaluated how informal caregivers' preferred role in decision-making affected their anxiety and depression one and three months after using the PtDA.^{20, 25} Informal caregivers with a passive-role preference and paired with the PtDA experienced a significantly greater increase in anxiety from one to three months than those with an active-role preference and paired with the PtDA ($p=0.021$) with a medium effect size (0.61). The same pattern occurred with depression ($p<0.007$, $d=0.71$). The investigators also sought to identify patient factors that predict the informal caregivers' preferred decision-making role, and found no correlation between a patient's age, gender, and diagnosis with this role. Other possible patient and caregiver characteristics that may make a caregiver more active or passive remain to be explored. Given that there is no current way to predict an informal caregiver's preferred role in

decision-making and that this influences the emotional distress caused by using a PtDA, it is imperative that future PtDAs assess for users' preferences within their contents.

Emotions surrounding decision-making and the use of PtDAs are complex. Anxiety and depression levels may not be completely related to the PtDA itself, as shown by the influence of the control material's tone and the informal caregiver's preferred role in decision-making.^{20, 25} There is a need for future studies to elaborate on factors influencing emotions while using a PtDA so that future PtDA designs can minimize negative outcomes. Despite the mixed impact of PtDAs on anxiety and depression measured in these studies, there is no evidence that patients or informal caregivers themselves perceived the tools as emotionally distressing. All reviewed studies eliciting feedback about the PtDA's acceptability received positive responses.^{6, 21, 22, 27}

2.2.4 Conclusion to Decision Aids in Serious Illnesses

Twelve papers published within the last ten years evaluated the effect of PtDAs designed for informal caregivers and patients facing a serious illness on decision quality, behavior, and emotions. Reviewed PtDAs improved decision quality and impacted behavior, matching conclusions in the Cochrane Review comparing PtDAs against usual care. The effect of PtDAs on user emotions was mixed. However, weaknesses in study methodology at times limited conclusions. Low initial enrollment of informal caregivers, high attrition rates, poor controls, among other issues were common. Future trials in this area must consider these issues to improve evidence quality and better develop understanding of this topic. In this way, PtDA design and implementation can be optimized for patients' and informal caregivers' learning benefit.

2.3.0 Palliative Care Information Needs

To learn more about PC information needs, we conducted a systematic review of the literature regarding informal caregivers' and community members' PC perceptions. From December 2019 through April 2020, we searched Ovid (Medline), APA PsychINFO, AMED,

CINAHL, PubMed, and Embase using the following as MeSH terms and as free keywords independently and in combination: *palliative care, perception, carer, caregiver, community, layperson*. We also searched references of included studies. We limited the review to articles published in English within the past ten years and to adult laypersons or informal caregivers. We reviewed titles and abstracts to ensure relevance to the proposed study.

We identified 11 papers, five papers using qualitative interviews,³¹⁻³⁵ and six papers discussing performances on PC attitudes surveys,^{12, 13, 36-39} half of which analyzed different populations who took the National Cancer Institute Health Info National Trends Survey 5, Cycle 2 (HINTS).^{13, 36, 37} Small samples (ranging from 10 to 71 subjects) and monolithic populations limited the interviews' generalizability. However, these papers as a group are generalizable since they all had similar results. The perception patterns across these studies provide insight into key issues future PC education efforts must address.

Subjects often paired PC benefits with EOL care and death. For instance, 90% of the 1162 HINTS responders with self-reported PC knowledge knew it offers social and emotional support along with pain and symptom management, but 59.3% of these subjects also believed PC's primary goal is extending time at the EOL.³⁶ Two other analyses of HINTS also demonstrated this pattern, with 49% of all participants¹³ and 40% of informal caregivers³⁷ equating PC with hospice. Additionally, while interviewees expected PC to manage symptoms and holistically support patients and family, they consistently described this care as a comfort to those who are dying.^{31, 32}

The association with EOL care negatively impacted perceptions on the quality and treatments PC offers. For example, 59% of 1518 surveyed laypersons did not know that PC is available early in the disease course. Subsequently, 45% did not know that PC and life-

prolonging care can be delivered concurrently.³⁹ Education about early PC is therefore crucial to overcoming this misconception. Due to the EOL care connection, caregivers interviewed by Collins, et al. considered PC a lesser treatment option, and interviewees often reported feeling that it is just “nursing care” meant to “make sure you’re comfortable”.³³ Since these informal caregivers along with other interviewed patient-caregiver dyads believed that PC is used as a last resort, they associated it with losing autonomy.^{31,33} Education clarifying that PC assists with ACP would address this misconception. Furthermore, when describing their concerns over losing autonomy, several interviewees referred to PC as the “institution” or “hospital.”³³ This implies a lack of awareness for other PC settings, underscoring the need for future education to explain all possible care sites.

Future PC education clearly must address the perceived connection between PC and EOL care. A likely cause for this association may be the popular technique of comparing PC to hospice.¹³ This has created a perception that PC is pre-hospice care, and this relationship to hospice has led to the EOL care connection. To overcome this, it is important to communicate about what PC is rather than what it is not, and refocus the message on PC as a necessity and comfort for patients and family.^{32, 40}

2.4.0 Review of Relevant Methodology

In this section, relevant methodology of previously described studies will be reviewed to further validate the proposed study design.

2.4.1 Study Design and Confounding Variables

An evaluation of study design types and confounding factors in the reviewed studies underscores the need for future trials to use strenuous methodology, such as an RCT, to assess PtDAs and PC education. Weaknesses in several trials are related to the type of study design. In three of the seven studies assessing gains in PC knowledge secondary to an educational

intervention, a lack of control group limited conclusions about the efficacy of the interventions.^{7, 9, 10} An RCT design would address this issue.

Studies considered and adjusted for a variety of possible confounding variables: the study subject's demographic information (age, gender, race, education level, income, employment and marital status), the relationship between the informal caregiver and patient (living with patient, planned involvement with care, relationship status to patient), the patient's illness characteristics and severity (type and stage of cancer, time since diagnosis, perceived health status), and prior PC knowledge or use. These are all logical confounders and will be assessed for in the proposed study. In addition, two papers found evidence that PtDAs have a varied impact on different informal caregiver populations, but which caregiver characteristics would be impactful is not completely understood.^{20, 25} Therefore, an RCT is an appropriate design as it minimizes the impact of the poorly understood confounding variables.

2.4.2 Study Population

Patterns related to the study population used in the reviewed studies justifies the need for more extensive evaluation of PC education in the setting of a newly diagnosed cancer.

Conducting a PC study within an oncologic setting is a logical choice because of the strong integration and support of PC in oncology. Almost half of the reviewed PC education papers studied cancer patients and informal caregivers.^{5, 7-9, 11} PC originated from this field and ASCO guidelines state that all advanced cancer patients should receive PC services ideally within eight weeks of their diagnosis.^{16, 41} As discussed in Section 2.1.3, guidelines and clearly documented feedback from study subjects support early PC education and use. Although two papers have studied cancer patients and informal caregivers early in the disease process, they did not objectively measure the interventions' impact on informal caregivers.^{9, 11}

2.4.3 Recruitment and Inclusion/Exclusion Criteria

In reviewed studies, there is a pattern of small sample sizes limiting external validity and conclusions. The proposed study will utilize thorough recruitment strategies and less restrictive inclusion and exclusion criteria to address modifiable causes of small study populations.

Past trials' recruitment methods inform the proposed trial's methodology. In five of the ten studies involving current patients and informal caregivers that specified recruitment methods, clinical staff identified and initially approached potential subjects during office visits.^{7, 8, 20, 21, 23,}
²⁷ As such, it is crucial that staff is well-aware of the study in order to maximize recruitment potential. To address this matter, McIlvennan, et al. heavily engaged with staff through emails and fliers, and recruited 100% of eligible patients and 90% of eligible informal caregivers in a pilot RCT.²³ Given the success, it is worthwhile to incorporate this approach into future studies. Furthermore, participants facing a serious illness experience high levels of stress and mortality rates, so they are liable to drop out of studies.⁶ As described in Section 2.2.1, another trial did not achieve statistical significance in part due to a recruitment error that did not account for losses to follow-up of study subjects.²⁰ Recruiting participants for enrollment goals that incorporate estimated loss to follow-up rates is essential for successful study of this population. Finally, investigators recruited informal caregivers through patients. Due to different patient and informal caregiver availabilities, four studies^{11, 18, 21, 26} noted a disproportion between enrolled patients and informal caregivers, two of which^{21, 26} recruited too few informal caregivers and measured limited outcomes. Utilizing less restrictive patient inclusion criteria mitigates this issue as it maximizes the patient population for informal caregiver recruitment.

The disease and outcomes of interest often dictated patient inclusion criteria. For cancer patients, it ranged from broad criteria, such as "advanced cancer,"¹⁸ to more narrow criteria, such as "metastatic breast cancer"⁷ or "newly diagnosed, localized prostate cancer."²⁶ Studies with

more narrow inclusion criteria were testing PtDAs that involved diagnosis-specific treatment options and considerations.^{7-9, 20, 26} For the purposes of the proposed study, broad criteria are acceptable since the PtDA is not disease-specific and guidelines call for PC in all advanced cancers.¹⁶ As discussed in Section 2.1.2, the use of a patient's treatment type as exclusion criteria was problematic and will not be included in the proposed study.⁵

The informal caregiver's relationship to the patient determined their inclusion eligibility in reviewed studies. Patients typically selected a family member who either knew the patient well or provided primary support to the patient. Three trials did not limit their definition to a family member, with one asking for "someone,"¹¹ and the others asking for "a friend or family member."^{21, 23} One study also specified that the informal caregiver be unpaid.²² The proposed study will incorporate both concepts into the typical informal caregiver inclusion criteria to reduce confusion about other types of carers and to be considerate of different social situations.

All studies excluded those who could not understand the PtDA's language to ensure participants had the capacity to understand the PtDA and make decisions. One study²⁶ excluded those with cognitive impairments and two others^{7, 8} psychiatric instability. Two studies also excluded those with a physical comorbidity, such as renal disease or pregnancy.^{10, 20} Physical comorbidities do not impact the ability to understand a PtDA, so they will not be considered in the proposed study. However, one treatment exclusion criterion, those with previous PC use, as they likely have high PC knowledge levels, creating a ceiling effect on knowledge score improvement. These exclusion criteria will apply to informal caregivers in the proposed study, as they are the proposed PtDA's users.

2.4.4 Decision Aid Delivery

Evaluation of the PtDAs in the reviewed studies provides information about delivery timing and formats to consider for the proposed study. The timing of the PtDA delivery in

relation to office visits varied across studies. Three studies permitted the PtDA to be delivered before, during, or after an office visit.^{6, 21, 23} While a flexible approach eases the incorporation of the PtDA into practice, inconsistent delivery schedules increase the risk of confounding factors. One study reported some nonsignificant measures, which may have been due to only 89.7% of the PtDA group receiving the PtDA.²¹ Designating a specific protocol for PtDA delivery timing minimizes the risk of this bias, and has been successfully implemented in other reviewed studies. For instance, study participants specifically received the PtDA prior to an office visit in three papers.^{11, 26, 27} The proposed study will also incorporate a more specific protocol, delivering the PtDA during the meeting in the which informal caregiver is recruited.

Reviewed studies formatted the PtDA as an online tool,¹⁹ a printed handout,^{7, 8, 22, 26} a video,¹⁸ a video or printed handout,^{21, 23} or a video with a printed handout.^{6, 11, 20, 27} There was no pattern between the PtDA format and outcome significance. Kozlov, et al. also found no significant difference in patient preference for a video or printed format of their intervention.⁴ It is reasonable for future studies to format the PtDA in a way that best suits the study design needs. Since the proposed PtDA delivery will occur during or shortly after an office visit and printed handouts are commonly used in this setting, a printed PtDA format is a logical choice.

2.4.5 Decision Aid Content

Reviewed studies revealed development standards along with informational and decision support needs to incorporate in the proposed PtDA. For referenced PtDA development guidelines, six did not report any standards,^{6-8, 18-20, 24, 26} one used the Medical Research Council developing complex interventions guide,²² and three used the International Patient Decision Aid Standards (IPDAS).^{11, 21, 23, 27} IPDAS also provided the basis for the primary outcomes in the Cochrane Review comparing PtDAs to usual care.²⁸ The IPDAS are evidence-based criteria for PtDA development and content.²⁸ According to IPDAS, PtDAs must include sufficient detail for

decision-making, an unbiased presentation of options, values-clarifying exercises, and guidance in deliberation. PtDAs must also be written at an eighth-grade reading level, assessed by the SMOG Readability Formula. Given the prevalent use of these criteria, the proposed study's PtDA will also model IPDAS guidelines.

As discussed in Section 2.3.0, it is critical to focus PC education on what it offers and not compare it to other services, such as hospice. The proposed PtDA will follow this suggestion while also incorporating information to address concrete educational needs identified in Section 2.3.0. The proposed PtDA will also assess for informal caregivers' preferred role in decision-making, which was found to effect the PtDA's emotional impact on users.²⁵ Given the importance of phrasing used for PC education, we referenced PC marketing materials in addition to official PC guidelines for definitions and explanations.^{40, 42, 43} The proposed PtDA, *Consider Palliative Care*, is in Appendix A.

2.4.6 Primary and Secondary Outcomes

Studies assessing PtDAs in serious illnesses and PC education have measured a variety of outcomes. As of yet, no study has assessed outcomes pertaining to knowledge, behavior, and emotional impact in informal caregivers of cancer patients using a PC education PtDA.

Nine reviewed studies evaluated patient and informal caregiver knowledge.^{4-8, 10, 18, 21, 23} Knowledge posttests across studies typically occurred immediately, one month, three months, or six months after the intervention. Only two papers assessed knowledge levels at six months, limiting the understanding of interventions' long-term impact.^{10, 21} However, the high drop-out rates in serious illness populations would require a large sample size to measure six-month knowledge levels as a primary outcome, which may not be feasible. Three studies also did not specify that study participants took a knowledge pretest, limiting insights about these interventions' impact on knowledge.^{5, 8, 9} For instance, as discussed in Section 2.1.1, Graul et al.

found no significant difference in knowledge scores between those who received PC education and those who did not, and it is not possible to rule out high baseline PC knowledge levels as a confounder without pretest scores.⁵ To maximize conclusions drawn about knowledge while maintaining a feasible sample size, the proposed study will evaluate PC knowledge differences between baseline and one month after the intervention as the primary outcome. As secondary outcomes, we will assess knowledge level differences between baseline and immediately after to ensure the PtDA has any effect, and between baseline and six months to estimate long term impacts of the PtDA. As discussed in Section 2.1.1, there are several palliative knowledge assessments available, including one by Matlock, et al., KOCO, PaCKS, and PaCKS 2.0. Of these options, PaCKs 2.0 is the most appropriate choice for the proposed study since it is not limited to PC in an oncologic setting, has a lower risk of guessing as a confounder, and has normative data measured by Kozlov, et al.¹²

Three studies evaluated study subjects' PC behaviors. Two measured PC preferences on preference scales immediately after or six months after the study activities.^{3, 10} Graul, et al. asked patients if they would like a referral immediately after the study activities and reviewed electronic medical records (EMR) at six months for PC appointment attendance.⁵ However, this study measured nonsignificant results and it is unclear if asking patients if they would like a referral confounded PC preference levels, so this may not be an appropriate measure to include in the future. Evaluating for PC appointment attendance at six months is a logical outcome as it provides patients ample time to attend an appointment and offers an objective PC preference measure. Searching the EMR enables investigators to evaluate this outcome regardless of the participants' enrollment status, but does not permit an evaluation of the decision quality, an important measure when studying behaviors. Five reviewed studies used the DCS

assessment to measure decision quality.^{6, 20-22, 25} This comprehensive tool is standard in the decision science field, so it is an appropriate measure to use in the proposed study at six months.

Finally, several studies evaluated PtDA acceptability for patients and informal caregivers. This included emotional impact, which was assessed with the Hospital Anxiety and Depression Scale (HADS).^{7, 22, 25} Given that PtDAs encourage users to address difficult decisions, anxiety may transiently increase,²¹ and it may be worthwhile to track changes over time, such as before, immediately after, and one month after the study activities. Some studies also interviewed patients and informal caregivers to determine if the PtDA contained balanced, relevant, and the right amount of information, and if they found the tool useful and recommendable.^{11, 22, 27} One study used an acceptability questionnaire instead, which offers a practical way to evaluate these outcomes immediately after using the PtDA, while the experience is still fresh.⁶

2.4.7 Sample Size Calculation

To calculate the sample size for the proposed study, we obtained data from nine sources: one comparing PtDAs to usual care,²⁸ one assessing PC knowledge in laypersons,¹² and seven evaluating the use of PtDAs for patients and informal caregivers in the setting of a serious illness.^{6, 7, 11, 19-21, 23} Overall, we calculate based on the information below that we need 254 informal caregivers, 127 per study arm, to detect a 1.69-point (standard deviation SD=4.77) mean difference in knowledge score improvement on the PaCKS exam between study arms, assuming an alpha of 0.05 and a beta of 0.20 for a two-tailed hypothesis. A total of 310 informal caregivers should be recruited to ensure the enrollment of 254 subjects.

The expected mean difference in knowledge score improvement between intervention and control groups is based on work by Stacey, et al. and Kozlov, et al.^{12, 28} Stacey, et al. analyzed knowledge assessment scores from 52 studies, and found that subjects who use a PtDA versus subjects who receive usual care scored an average of 70/100 and 57/100 on a standardized

metric, respectively.²⁸ It is reasonable to expect similar results in the proposed study, since it is also evaluating a PtDA against usual care.

Kozlov, et al. assessed knowledge about PC in 152 adult laypersons using PaCKS 2.0.¹² The average PaCKS 2.0 score was 5.25/13 (SD=4.77). The proposed study will use PaCKS 2.0 to evaluate informal caregiver PC knowledge. Since the study population is composed of informal caregivers for newly diagnosed cancer patients, the study population at baseline is similar to the adult laypersons studied by Kozlov, et al. Therefore, a logical mean pre-test score in both study arms is 5.25/13. After undergoing study activities, it is reasonable to expect the PtDA group to achieve a mean post-test score of 9.10/13, the equivalent of 70/100 for the PaCKS exam. The usual care should achieve a mean post-test score of 7.41/13, the equivalent of 57/100. Between the pre- and post-tests, the PtDA group and the usual care group should respectively improve their scores by 3.85 points and 2.16 points, for a mean 1.69-point (SD=4.77) improvement difference in knowledge scores between groups.

Seven trials assessing PtDAs for patients and informal caregivers in the setting of a serious illness provide insight into the expected loss-to-follow-up rate for the proposed study.^{6, 7, 11, 19-21, 23} An average loss-to-follow-up rate of 22.06% was observed within the first month of these trials. The proposed study will likely experience a similar rate since it utilizes the same population and time frame.

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Chapter Three: Study Methods

3.1 Study Design

We will conduct a prospective, single-blinded, single-center RCT to investigate the impact of a PtDA compared to usual care on palliative care knowledge in informal caregivers of newly diagnosed advanced cancer patients. We will also evaluate for palliative care utilization, decision quality, and the PtDA's emotional impact and acceptability.

3.2 Study Population and Sampling

The study population will include informal caregivers selected by advanced cancer patients diagnosed within the past eight weeks who are being treated at the Smilow Cancer Hospital outpatient clinic. Smilow Cancer Hospital is located within Yale New Haven Hospital in New Haven, CT and is Connecticut's largest cancer care provider, treating approximately 48% of the state's 20,000 new cancer diagnoses annually.¹ Smilow Cancer Hospital also contains an inpatient and outpatient PC Program. We will utilize consecutive sampling and identify every eligible informal caregiver until we reach our enrollment goal of 310.

3.3 Inclusion Criteria

Informal caregivers will be recruited from eligible patients. Eligible patients are over the age of 18 and have been diagnosed with advanced cancer within the past eight weeks, which includes those with distant metastases, late-stage disease, and/or a prognosis of six to 24 months.² Patients can be receiving chemotherapy, radiation, and surgery.

Informal caregivers are selected by patients as an unpaid friend or family member who provides primary support. They must be over the age of 18 and speak English.

3.4 Exclusion Criteria

Patients and informal caregivers will be excluded if they have previously used palliative care or if the patient's healthcare provider informs us that they are inappropriate for the study, such as the presence of psychiatric instability or cognitive impairment.

3.5 Study Protection and Confidentiality

Prior to recruitment, we will obtain approval from the Institutional Review Board (IRB), a commission of the Human Research Protection Program at Yale University. Before baseline data collection, a research assistant (RA) will provide all interested and eligible patients and informal caregivers verbal and written information about the trial. We will require eligible informal caregivers to sign an IRB-approved consent form outlining the purpose and benefits of the research, possible adverse effects, confidentiality and privacy practices, and study procedures. The consent form will also inform participants that they can withdraw from the study at any time without the need for an explanation and without an effect on the patient's or informal caregiver's medical care. Contact information for the principal investigator and research personnel will be provided. A sample consent form is included in Appendix G.

We will perform all study procedures following Health Insurance Portability and Accountability Act (HIPAA) regulations. We will use participant ID numbers on outcome surveys, deidentify all patient information and data as soon as possible, and store it on password-protected, encrypted servers only accessible to appointed research team members. All research team members and clinical staff involved in this study will complete HIPAA training prior to the study's initiation.

3.6 Recruitment

We will identify potential patients through medical, radiation, and surgical oncology providers at Smilow Cancer Center, who will approach potentially eligible patients to determine interest in the study. An RA will meet with interested patients to confirm eligibility, explain the trial's goals and procedures, and obtain informed consent. The RA will ask the patient to select an eligible informal caregiver. The RA will meet with the informal caregiver to determine interest, confirm eligibility, and obtain informed consent. It is not necessary for the informal

caregiver to be present at the office visit in which the patient was recruited. The RA can meet with the informal caregiver at another convenient time and location to review the trial's purpose and procedures and obtain consent.

Prior to recruitment, we will email Smilow Cancer Center providers detailing trial procedures, background information and goals. In the email, we will review eligibility requirements and ask providers to identify and refer potentially eligible patients and informal caregivers to research team members. We will then send providers bimonthly emails as a reminder of the trial and to provide an update on recruitment efforts. An example email is provided in Appendix H.

3.7 Study Variables and Measures

After baseline data collection and randomization, the RA will provide the intervention group a paper version of the PtDA. The RA will briefly explain the PtDA's purpose and contents, and answer questions. Informal caregivers will independently complete the PtDA, but may ask research personnel any follow-up questions. In contrast, the control group will receive usual care after baseline data collection and randomization. With usual care, providers will introduce patients and informal caregivers to palliative care. There are no guidelines dictating how providers should approach palliative care education and conversations, so informal caregiver experiences will vary in the control group.

As discussed in Section 2.4.6, the primary outcome will be the mean difference in palliative care knowledge score improvement on PaCKS 2.0 from baseline to one month after the study between the intervention and control groups.

We will measure a variety of secondary outcomes. We will compare the mean difference in palliative care knowledge score changes on PaCKS 2.0 from baseline to immediately after and from baseline to six months after the study between study arms. We will also evaluate the

PtDA's behavioral impact and compare the percentage of informal caregivers who intend to or have utilized palliative care at six months between study arms. We will then assess decision quality and compare mean DCS scores related to the decision whether or not to utilize palliative care between the study arms. Finally, we will evaluate measures related to the PtDA acceptability. We will compare the mean difference in anxiety and depression level changes from baseline to immediately after, one month after, and six months after the study between study arms. We will also measure the percentage of intervention informal caregivers with positive, neutral, or negative perceptions of the PtDA's content and presentation immediately after the study. Further details on measurement scales are provided in Section 3.12.

Potential confounders include age, gender, race, education level, income, employment, marital status, the relationship between the informal caregiver and patient (living with patient, planned involvement with care, relationship status to patient), the patient's illness characteristics and severity (cancer type and stage, time since diagnosis, perceived health status), and prior palliative care knowledge.

3.8 Assignment to Intervention

We will randomize informal caregivers using the sequentially numbered, opaque, sealed envelopes method after they provide consent and complete baseline assessments. The RA will open the next envelope in the sequence to randomly assign the informal caregiver to a group.

Given the nature of the intervention and control, the informal caregiver and RA collecting data at baseline and immediately after the study will not be blinded. We will change the RA collecting data from each informal caregiver at one-month and six-month follow-up sessions to blind data collection at these times. The outcome assessor will be blinded throughout the trial.

3.9 Adherence

We will report adherence as the proportion of informal caregivers who state they read the PtDA in its entirety during immediate follow-up data collection.

To mitigate follow-up losses, we will offer informal caregivers options for one-month and six-month follow-up data collection surveys. Data collection can occur by mail, over the phone, or in-person with an RA. The RA can meet with the informal caregiver at a location that is convenient for them.

3.10 Adverse Events

Using the PtDA may increase anxiety and depression levels. All adverse events will be reported in writing to the IRB. We will also provide participants with contact information for the principal investigator and research personnel in case of concerns.

3.11 Data Collection

Study subjects will meet with research personnel three times for data collection: once for baseline and immediate follow-up testing, once at one month, and once at six months. An RA will call participants two weeks in advance to schedule one-month and six-month follow-ups.

We will assess potential confounding variables with a baseline characteristics survey. We will measure palliative care knowledge using PaCKS with an unsure answer option.³ Informal caregivers will report utilization of or plans to use palliative care and the associated decision quality using DCS.⁴ We will assess anxiety and depression using HADS.⁵ Informal caregivers in the intervention group will complete the Ottawa Decision Aid Library Acceptability Scale modified for our PtDA's topic.⁶ We include the surveys and a data collection timeline in Appendices B-F.

3.12 Sample Size

Using Power and Precision statistical software and data from reviewed studies, we calculate that we will need 254 informal caregivers, 127 per study arm, to detect a 1.69-point (SD=4.77) mean difference in knowledge score improvement on PaCKS 2.0 between study arms,

assuming an alpha of 0.05 and a beta of 0.20 for a two-tailed hypothesis. To adjust for a 22.06% loss-to-follow-up rate, we will recruit 310 informal caregivers to ensure the enrollment of 254 subjects. Section 2.4.8 provides a thorough rationale for values used in this calculation.

Appendix H provides an image of the data inputs in the Power and Precision statistical software.

3.13 Analysis

We will perform analyses under the intention-to-treat principle with a significance level of $p \leq 0.05$. Continuous variables will be described as a mean value with a standard deviation and categorical variables as a percentage. We will calculate descriptive statistics for demographic and clinical characteristics, baseline outcome measures, and PtDA acceptability scores. We will measure the baseline equivalence between study arms using t-tests (parametric) or Wilcoxon Rank sum tests (nonparametric) for continuous variables and chi-square analyses for categorical variables. We will use a t-test to compare knowledge score changes, anxiety and depression levels, and DCS scores between study arms. We will use chi-square analysis to compare palliative care usage between study arms. We will account for any significantly different baseline variables using simple linear or simple logistic regression.

3.14 Timeline and Resources

The study period will last two years. This includes an 18-month rolling recruitment period to maximize the sample size while allowing for six months to complete follow-up data collection.

The study will require the following personnel: one principle investigator, one co-principle investigator, two RAs for data collection and entry, one outcome assessor, and one data safety monitoring committee. Medical, radiation, and surgical oncology providers at Smilow Cancer Hospital will assist in identifying potential subjects.

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Chapter Four: Discussion

4.1 Advantages and Disadvantages

The advantages of the proposed study lie in the study population and rigorous approach to measuring outcomes. By recruiting within a newly diagnosed advanced cancer patient population, the proposed study will fulfill ASCO guidelines. Recruiting in this population will also address a gap in palliative care education research, since only two studies in our systematic review used subjects who were early in the disease trajectory.^{1,2} There remains a need to objectively evaluate the impact of palliative care education in this population, as well. Our study incorporates successes and weaknesses of previous trials investigating serious illness PtDAs to ensure rigorous and objective testing of the proposed palliative care PtDA. Using an RCT design will minimize the impact of unknown informal caregiver characteristics on the PtDA's efficacy. When studying knowledge, measuring pretest scores will permit us to evaluate for high baseline knowledge levels confounding posttest results. Immediate posttest scores will show if the PtDA has any effect on knowledge. Knowledge scores at one and six months will provide insight into long-term effects of the PtDA, which is essential for changing behaviors. Furthermore, our study builds on lessons learned from reviewing various palliative care knowledge tests. Using PaCKS 2.0 will address concerns such as guessing as a confounder and permit us to use a scale that has national normative data.³ Overall, our study design is optimized to objectively assess the PtDA's impact, particularly on palliative care knowledge. Understanding its effect on knowledge is important as it is one of the primary modifiable reasons people do not use palliative care.^{4,5}

The proposed study design contains several limitations. As with other studies involving populations facing a serious illness, managing high losses to follow-up and recruitment will be a challenge. However, we account for the expected drop-out rate in our recruitment goals. Our study design maximizes recruitment potential by engaging with clinical staff, using broad

inclusion and exclusion criteria, and using a high-volume cancer center. Also, due to the nature of the intervention, informal caregivers and the RA administering the PtDA will not be blinded. The study design nonetheless blinds as many components as possible by changing the RA at one and six months and keeping outcome assessment blinded throughout the study. Providers' varying comfort levels with palliative care is another potential source of bias. This could affect how they introduce palliative care to patients and informal caregivers receiving usual care, subsequently impacting these subjects' palliative care attitudes and behaviors. However, diverse approaches within the usual care group is acceptable here because our study seeks to compare the PtDA to the current reality of clinical practice. Varying provider communication abilities and comfort with palliative care is a part of this reality.⁶ Our estimate of the PtDA's impact on palliative care use is subject to bias, as well. Those who agree to participate in the study may be more amenable to palliative care at baseline than those who decline, which may falsely elevate usage at six months. Also, palliative care use may be affected by the subject's ability to schedule an appointment. To account for this issue, we provide instructions in the PtDA for those who want palliative care and use a cancer center with an active palliative care team and clinic on site.

4.2 Future Directions

Next steps depend on the results of this study. If we measure nonsignificant results, it may be necessary to redesign the PtDA or consider another approach to palliative care education. If we measure significant results, we could use the momentum gained from the trial's success and test the PtDA in a larger population. In this way, we could have a large enough sample size to measure palliative care knowledge and use at six months as primary outcomes. Thus, we could gain more definitive insight into the PtDA's long-term impact on knowledge and behaviors. Another option would be to study the PtDA in another population with a serious illness and gain insight into the PtDA's efficacy in a clinical environment that may not be as familiar with

palliative care as oncology. The data behind the PtDA would then also better align with the mission to offer palliative care to all people facing a serious illness.

4.3 Significance and Impact

Palliative care benefits patients and informal caregivers, yet relatively few use it.^{4,5,7} A lack of accurate palliative care knowledge is one of the primary reasons people do not use this service.^{8,9} The proposed study will provide insights into the impact of a PtDA on palliative care knowledge and behaviors of informal caregivers of newly diagnosed advanced cancer patients.

If the proposed PtDA significantly improves palliative care knowledge, it will provide a useful tool for clinicians to use to discuss palliative care. It is of particular importance that clinicians are able to communicate about this service since patients and their families expect providers to initiate education about palliative care.^{10,11} Furthermore, providers are encountering patients and informal caregivers in need of palliative care more frequently. The population in the US is aging and living longer with significant illness burden, so there are more people with complex care needs that palliative care addresses.¹² As clinicians become increasingly exposed to these kinds of patients and their informal caregivers, the ability to effectively communicate will become of greater importance in clinical practice. Currently, however, providers may not have adequate palliative care knowledge or feel comfortable communicating about palliative care topics.⁶ A PtDA about palliative care could be of great use to clinicians to overcome these barriers and meet the demand for quality palliative care education.

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Appendix A: Decision Aid

Consider Palliative Care: Should I Use Palliative Care?

Step 1 The Facts	Step 2 Compare Options	Step 3 Your Values	Step 4 Your Decision
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Your Options

Your Options Include:

- Add palliative care to your or your family member's treatment plan.
- Use usual care.

Step One: The Facts

What Is Palliative Care?

Palliative care is specialized medical care for all patients with a serious illness and their families. It can be provided together with curative care.

The goal of palliative care is to improve quality of life for patients and their families. It provides relief from symptoms, side effects, and stress that happen with a serious illness. It provides another layer of support throughout the illness.

What Services does Palliative Care Include?

Palliative care has a whole-person approach to caring for patients and their families. The services you receive are based on your needs and values.

Services include:

- Expert care for pain and other symptoms, like nausea, fatigue, or shortness of breath.
- Help in navigating the health care system and understanding choices for care.
- Help in identifying goals of care and making a care plan.
- Coordination of care throughout the illness.
- Emotional and social support.
- Spiritual support.

Who Provides Palliative Care?

A team of specially trained doctors, PAs, APRNs, nurses, social workers, chaplains, and other professionals provide palliative care. You will work with members of the team based on your needs.

Palliative care team members work closely with each other and with your other clinicians to promote continuity of care.

Who Can Receive Palliative Care?

Patients of any age and stage of an illness are eligible. You can receive curative treatment along with palliative care.

Family members are also eligible.

Where Can You Receive Palliative Care?

If feasible, palliative care is provided in a setting preferred by the patient and family. Palliative care is available in hospitals, clinics, skilled care facilities, at home and other locations.

Who Pays for Palliative Care?

Most insurances, including Medicare and Medicaid, cover palliative care.

Palliative Care Benefits	Palliative Care Risks
<ul style="list-style-type: none">▪ Patients who use palliative care may live longer than those who do not.¹▪ Across studies, patients and family who used palliative care reported a better quality of life than people who did not use palliative care.<ul style="list-style-type: none">- Patients had better physical and emotional well-being and less depression.^{2,3}- Family caregivers had less regret and better mental health. They also had better spiritual, physical, and social well-being.^{2,4}▪ Patients who use palliative care may spend less time in the hospital than those who do not get palliative care.⁵▪ Using palliative care may improve patients' and family members' satisfaction with care. They may be more likely to receive preference-matched care than those who do not use palliative care.²	<ul style="list-style-type: none">▪ You may incur additional costs using palliative care.<ul style="list-style-type: none">- While most insurances cover palliative care, deductibles, copays, and out-of-network costs still apply.▪ Some medications used in palliative care, like opioids for pain, have serious side effects.<ul style="list-style-type: none">- Palliative care clinicians are trained to safely use these medications.

Step Two: Compare Your Options

	Use Palliative Care	Use Usual Care
What is Usually Involved?	<ul style="list-style-type: none"> ▪ Patients and families receive treatments and diagnoses from their regular clinician. ▪ Patients and families also work with other professionals to address different needs. For example, they may: <ul style="list-style-type: none"> - Have a family meeting to discuss goals of care. - Meet with a clinician to manage treatment side effects. 	<ul style="list-style-type: none"> ▪ Patients and families receive treatments and diagnoses from their regular clinician.

Step Three: Your Values

Before completing this section, it is important to consider how you prefer to make decisions about your care. Please mark the square that best shows your feelings.

I prefer to take an active role in making care decisions.	I prefer to leave decision-making to my medical providers.
<input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/>	<input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/>
Strongly Agree	Neutral
	Strongly Agree

If you prefer to have a less-involved approach in deciding your care, you may consider not completing the rest of this section.

Your feelings about your care are important. Think about what matters most to you in this decision, and please mark the square that best shows your feelings.

Reasons to Use Palliative Care	Reasons Not to Use Palliative Care
I want to get more support from healthcare professionals during this illness.	I am satisfied with the support I receive from my community during this illness.
<input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/>	<input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/>
Strongly Agree	Neutral
	Strongly Agree
I am interested in a whole-person approach to medical care.	I am satisfied with the care I get from my regular clinician.
<input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/>	<input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/> ————— <input type="checkbox"/>
Strongly Agree	Neutral
	Strongly Agree

Reasons to Use Palliative Care	Reasons Not to Use Palliative Care
<p>I want to get more support in creating future care plans.</p>	<p>I am confident in my ability to plan for future care.</p>
<p>I am not worried about the cost of palliative care.</p>	<p>I am worried about the cost of palliative care.</p>
<p>My other important reasons:</p> <div style="border: 1px solid black; height: 150px; width: 100%;"></div>	<p>My other important reasons:</p> <div style="border: 1px solid black; height: 150px; width: 100%;"></div>

Step Four: Your Decision

Now that you have thought about the facts and your values, you may have a general idea on where you stand on this decision. Please mark the square that best shows your feelings.

<p>Using Palliative Care</p>	<p>Not Using Palliative Care</p>
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Decide What's Next:

- Do you understand the options available to you? Yes No
- Are you clear on what benefits and risks matter most to you? Yes No
- Do you have enough support and advice from others to make a choice? Yes No

How sure do you feel about your decision?

<input type="checkbox"/>						
Not At All Sure			Somewhat Sure			Very Sure

Please mark what you need to do before you make your decision:

- I am ready to take action.
 - Feel free to discuss your decision with your regular clinician.
 - If you want to use palliative care, your regular clinician can help you with a referral.

- I want to discuss this option with others.

- I want to learn more about my options.
 - Here is a helpful link: <https://getpalliativecare.org>

Use the following space to list questions, concerns, and next steps. Feel free to share this form with your clinician and loved ones.

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Appendix B: Data Collection Timeline

Study Arm	Baseline	Immediate Follow Up	One-Month Follow Up	Six-Month Follow Up
Intervention Group (PtDA)	<ul style="list-style-type: none"> ● Baseline Characteristics ● HADS ● PaCKS* 	<ul style="list-style-type: none"> ● Acceptability ● HADS ● PaCKS 	<ul style="list-style-type: none"> ● HADS ● PaCKS* 	<ul style="list-style-type: none"> ● DCS - Palliative Care Use ● HADS ● PaCKS
Control Group (usual care)	<ul style="list-style-type: none"> ● Baseline Characteristics ● HADS ● PaCKS* 	<ul style="list-style-type: none"> ● HADS ● PaCKS 	<ul style="list-style-type: none"> ● HADS ● PaCKS* 	<ul style="list-style-type: none"> ● DCS - Palliative Care Use ● HADS ● PaCKS

*Primary outcome. DCS, Decisional Conflict Scale; HADS, Hospital Anxiety and Depression Scale; PaCKS, Palliative Care Knowledge Scale.

Appendix C: Palliative Care Knowledge Scale

Below are some questions about a type of care called palliative care. Please answer the questions below by circling True, False, or I don't know. If you do not know the answer, do not guess. Instead, respond with "I don't know."

1. A goal of palliative care is to address any psychological issues brought up by serious illness.

True

False

I don't know

2. Stress from serious illness can be addressed by palliative care.

True

False

I don't know

3. Palliative care can help people manage the side effects of their medical treatments.

True

False

I don't know

4. When people receive palliative care, they must give up their other doctors.

True

False

I don't know

5. Palliative care is exclusively for people who are in the last 6 months of life. True

True

False

I don't know

6. Palliative care is specifically for people with cancer. True

True

False

I don't know

7. People must be in the hospital to receive palliative care.

True

False

I don't know

8. Palliative care is designed specifically for older adults. True

True

False

I don't know

9. Palliative care is a team-based approach to care. True

True

False

I don't know

10. A goal of palliative care is to help people better understand their treatment options.

True

False

I don't know

11. Palliative care encourages people to stop treatments aimed at curing their illness.

True

False

I don't know

12. A goal of palliative care is to improve a person's ability to participate in daily activities.

True

False

I don't know

13. Palliative care helps the whole family cope with a serious illness.

True

False

I don't know

Appendix D: Acceptability Scale

My Thoughts on the Education Package on Palliative Care

We would like to know what you think about the education package you have just received.

1. Please rate each section, by circling 'poor', 'fair', 'good', or 'excellent' to show what you think about the way the information was presented on:

Goals of Palliative Care	poor	fair	good	excellent
Palliative Care Services	poor	fair	good	excellent
Provision of Palliative Care	poor	fair	good	excellent
Benefits of Palliative Care	poor	fair	good	excellent
Risks of Palliative Care	poor	fair	good	excellent
Different Care Options	poor	fair	good	excellent

2. The length of the presentation was: (*check one*)

- Too long
- Too short
- Just right

3. The amount of information was: (*check one*)

- Too much information
- Too little information
- Just right

4. I found the presentation: (*check one*)

- Slanted towards adding palliative care
- Slanted towards usual care
- Balanced

5. What did you think of the rest of the personal worksheet?

Did it make the decision: (*check one*)

- Easy
 - More difficult
 - No effect
 - Comments:
-

6. Do you think we included enough information to help people decide on palliative care or usual care for treatment? (*check one*)

- Yes
- No
- Comments:

7. What did you like about the decision aid?

8. What suggestions do you have to improve the decision aid?

Appendix E: Decisional Conflict Scale

My Difficulty in Making this Choice

A. Which treatment option do you prefer? Please check one.

- Adding palliative care to my or my family member's treatment plan.
- Using usual care.
- Unsure.

B. Considering the option you prefer, please answer the following questions:

	Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
I know what options are available to me.					
I know the benefits of each option.					
I know the risks and side effects of each option.					
I am clear about which risks and side effects matter most to me.					
I am clear about which is more important to me (the benefits or the risks and side effects).					
I have enough support from others to make a choice.					
I am choosing without pressure from others.					
I have enough advice to make a choice.					
I am clear about the best choice for me.					
I feel sure about what to choose.					
This decision is easy for me to make.					
I feel I have made an informed choice.					
My decision shows what is important to me.					
I expect to stick with my decision.					
I am satisfied with my decision.					

AM O'Connor, Decisional Conflict Scale. ©1993 [updated 2005]. Available from www.ohri.ca/download

Appendix F: Hospital Anxiety and Depression Scale

Instructions: Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he or she will be able to help you more. This questionnaire is designed to help your doctor know how you feel. Read each item and circle the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

I feel tense or "wound up":	A
Most of the time	3
A lot of the time	2
From time to time, occasionally	1
Not at all	0

I feel as if I am slowed down:	D
Nearly all the time	3
Very often	2
Sometimes	1
Not at all	0

I still enjoy the things I used to enjoy:	D
Definitely as much	0
Not quite so much	1
Only a little	2
Hardly at all	3

I get a sort of frightened feeling like "butterflies" in the stomach:	A
Not at all	0
Occasionally	1
Quite Often	2
Very Often	3

I get a sort of frightened feeling as if something awful is about to happen:	A
Very definitely and quite badly	3
Yes, but not too badly	2
A little, but it doesn't worry me	1
Not at all	0

I have lost interest in my appearance	D
Definitely	3
I don't take as much care as I should	2
I may not take quite as much care	1
I take just as much care as ever	0

I can laugh and see the funny side of things:	D
As much as I always could	0
Not quite so much now	1
Definitely not so much now	2
Not at all	3

I feel restless as if I have to be on the move:	A
Very much indeed	3
Quite a lot	2
Not very much	1
Not at all	0

Worrying thought go through my mind	A
A great deal of the time	3
A lot of the time	2
From time to time, occasionally	1
Only occasionally	0

I look forward with enjoyment to things:	D
A much as I ever did	0
Rather less than I used to	1
Definitely less than I used to	2
Hardly at all	3

I feel cheerful:	D
Not at all	3
Not often	2
Sometimes	1
Most of the time	0

I get sudden feelings of panic	A
Very often indeed	3
Quite often	2
Not very often	1
Not at all	0

I can sit at ease and feel relaxed	A
Definitely	0
Usually	1
Not Often	2
Not at all	3

I can enjoy a good book or radio or TV program	D
Often	0
Sometimes	1
Not often	2
Very seldom	3

Please check you have answered all the questions.

Scoring:

Total score: Depression (D)_____

Anxiety (A)_____

0-7: Normal

8-10: Borderline

11-21: Abnormal

Appendix G: HIC Consent Form

Created using 200 FR.1 HIC Consent For Participation in a Research Project Template

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT 200 FR. 1 (2016-1)

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: *Considering Palliative Care: A Decision Aid to Improve Palliative Care Knowledge*

Principal Investigator: *[Insert name.]*

Co-Principal Investigator: *[Insert name.]*

Funding Source: *[Insert name of company or agency.]*

Invitation to Participate and Description of Project

We are inviting you to participate in a research study designed to look at *Considering Palliative Care (CPC)*, a decision aid to educate informal caregivers (a friend or family member providing support to a patient) about palliative care. You have been asked to participate because you were nominated by a newly diagnosed cancer patient as an unpaid friend or family member who provides support to the patient and you expressed interest in participation to the patient's oncology provider.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This permission form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participating in this study, you will be asked to complete baseline questionnaires about your demographic and clinical characteristics, and anxiety and depression levels. You will also complete a palliative care knowledge test. These questionnaires are explained in further detail below. Then, a research team member will randomly assign you to either receive *CPC* or usual care. If you are assigned to receive *CPC*, the research team member will provide this to you along with a brief overview of the aid at this time. You will complete *CPC* on your own at this time. You will have 30 minutes to complete the decision aid, although you will be able to take additional time if you need it. The research member will also be available to answer any questions you may have while completing the aid. If you are assigned to receive usual care, you will not receive any materials at this time. Instead, you will be provided information about palliative care at your provider's discretion. After completing the decision aid or being assigned to usual care,

you will complete a follow-up questionnaire for anxiety and depression levels and a follow-up palliative care knowledge test. Those assigned to receive *CPC* will also complete a survey regarding their opinions on the decision aid's content presentation.

You will complete follow-up surveys one-month and six-month after the initial meeting, as well. A member of the research team will call two weeks in advance to schedule these follow-ups. To complete these questionnaires, you may either meet with a research team member in person, speak with a research team member over the phone, or mail your completed forms to the research team. At one month, you will complete a palliative care knowledge test and a questionnaire regarding anxiety and depression levels. At six months, you will complete a questionnaire where you will report if you or the patient have plan to or have used palliative care. You will also complete a palliative care knowledge test and a questionnaire about anxiety and depression levels.

A description of this clinical trial will be available on, <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Description of Questionnaires

You will complete multiple questionnaires as part of this study. Each questionnaire can be completed within a few minutes. You will either complete a paper copy of the forms or a research team member will complete them with you over the phone. We will assess your palliative care knowledge with a test called Palliative Care Knowledge Scale (PaCKS) by Kozlov, et al., which consists of 13 true or false questions about palliative care. We will assess your decision whether or not to use palliative care along with decisional conflict associated with this decision with a questionnaire called Decisional Conflict Scale (DCS) by O'Connor, et al., which consists of 16 questions rated on a 1-5 Likert scale. We will assess your anxiety and depression levels with a questionnaire called Hospital Anxiety and Depression Scale (HADS) by Zigmond, et al. which consists of 14 questions rated on a 0-4 Likert scale. Those who receive *CPC* will complete an acceptability questionnaire by O'Connor, et al., which consists of eight questions regarding your opinions on *CPC*.

Risks and Inconveniences

- Making decisions in the setting of an advanced illness can be stressful. Using *CPC* may increase your anxiety and depression levels. We will do our best to ensure you feel as supported as possible within our means.
- There is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Benefits

- This research may clarify a method to educate patients and informal caregivers about palliative care. A decision aid such as *CPC* may be a promising way to improve palliative care knowledge.

- This research may benefit society in general through contributions to clinical practice knowledge.
- This research may not directly benefit you.

Economic Considerations

- You will not be paid to participate in this study.
- You will not have to pay to participate in this study. The only cost to you is your transportation to and from study visits.

Confidentiality

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. Information will be kept confidential by using only participant ID numbers on outcome questionnaires and deidentifying information within two weeks and stored on a password-protected, HIPAA-compliant, encrypted servers. The information will be stored in its deidentified form indefinitely. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific permission for this activity is obtained.

Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

Voluntary Participation and Withdrawal

You are free to choose not to participate and if you do decide to become a subject you are free to withdraw from this study at any time during its course. Refusing to participate or withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). If you decide not to participate or if you withdraw, it will not harm your relationship with your own doctors or with Yale-New Haven Hospital, Smilow Cancer Hospital. However, you will not be able to enroll in this study and receive study materials or procedures in you do not allow use of your information as part of this study.

You have the right to withdraw their data after collection and before deidentification; however, once data has been deidentified, you will not be able to withdraw your data.

The researchers may withdraw you from participating in the research if necessary.

You do not give up any of your legal rights by signing this consent form.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the permission form carefully – as long as you feel is necessary – before you make a decision.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this permission form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject: _____

Signature: _____

Relationship: _____

Date: _____

Signature of Principal Investigator

Date

or

Signature of Person Obtaining Permission

Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator [*name and phone number*] or Co-Principal Investigator [*name and phone number*].

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

****Note that the signature of two parents is required for certain types of research as required by the HIC (45 CFR § 46.406)****

Appendix H: Sample Outreach Email

To whom it may concern,

We are researchers from the Yale School of Medicine and Yale PA Program conducting a study evaluating the use of a decision aid to educate informal caregivers of newly diagnosed advanced cancer patients about palliative care.

Despite the known benefits of palliative care, its service remains misunderstood and underutilized amongst patients and their families. Decision aids are clinical tools that may be useful in educating patients and their families about palliative care as they are designed to navigate decisions dependent on personal values. In our study, we will provide informal caregivers either a decision aid about palliative care or provide them usual care, meaning that providers will approach palliative care education and referrals as they typically do. We will then assess their knowledge about palliative care and utilization trends.

In order to complete our study, we need your assistance with recruitment. Please refer suitable and interested advanced cancer patients diagnosed within the last eight weeks and their informal caregivers to our research team. While our study focuses on informal caregivers, it is not necessary for them to be at the appointment with the patient. We will work with the informal caregiver to arrange a meeting with our team to determine eligibility.

We appreciate your assistance and please feel free to reach out to our team with any questions or concerns.

Thank you,

[Name]

Principle Investigator

[phone number]

[email address]

[School affiliation]

[Name]

Co-Principle Investigator

[phone number]

[email address]

[School affiliation]

Appendix I: Sample Size Calculation

Sample size calculation based on a t-test calculator assuming normal distribution:

- Alpha (Type I Error, Level of significance): 0.05, two-tailed hypothesis
- Beta (Type II Error): 0.20, corresponding to a power of 80%
- Expected mean difference between intervention and control groups: 1.69 points on PaCKS exam
- Standard Deviation: 4.77 points on PaCKS exam

Result: **n=254 informal caregivers** (127 for each study arm)

Power And Precision 4 - [t-test for two independent samples with common variance]

File View Options Tools Scenarios Help

Group	Population Mean	Standard Deviation	N Per Group	Standard Error	95% Lower	95% Upper
control 7.41-5.25	2.16	4.77	127			
intervention 9.1-5.25	3.85	4.77	127			
Mean Difference	-1.69	4.77	254	0.60	-2.87	-0.51

Alpha= 0.050, Tails= 2

Power 80%

The program displays power

For the given effect size (population means of 2.16 vs. 3.85), SD (4.77), sample sizes (127 and 127), and alpha (0.050, 2-tailed), power is 0.803.

This means that 80% of studies would be expected to yield a significant effect, rejecting the null hypothesis that the two population means are equal.

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Sample size factoring in 22.06% drop-out rate: **n=310 informal caregivers** (155 for each study arm)

Calculated using:

Power and Precision. Version 4.0. Biostat Inc. Englewood, New Jersey.

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