ORIGINAL RESEARCH

Feasibility Testing of an APRN-Led Model of Care for Transition of Patients After Completion of Phase I Trials

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Authors' disclosures of conflicts of interest are found at the end of this article.

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Abstract

Background: Patients on clinical trials experience numerous quality of life (QOL) concerns, including those associated with advancing disease. This pilot project tested the feasibility and initial outcomes of an advanced practice registered nurse (APRN)-led intervention for patients with gastrointestinal (GI) tumors transitioning after completing a phase I trial. **Objectives:** The objectives were to (1) Develop the "Transitions" care plan intervention based on prior research to support patient QOL including symptom management, psychosocial and spiritual support, and care after trial completion; (2) Test the feasibility of the intervention in a sample of patients with GI tumors; and (3) Evaluate the impact of the Transitions care plan intervention on improved care and QOL. **Methods:** A single-group, convenience sample of patients with GI tumors completing phase I clinical trials was accrued at a National Cancer Institute–designated Comprehensive Cancer Center in the western US. Patients completed questionnaires at baseline, 3 months, and 6 months. Interviews were conducted at 3 months for further understanding of patient needs. A Transitions care plan for the patient was developed by the APRN in collaboration with the patient and medical oncologist. Chart audits were conducted to capture supportive services referrals and completions. Key variables included domains of QOL, distress, and use of supportive care services. **Results:** Patients (N = 37) had significant needs for support across all QOL domains. The Transitions care plan model was valuable in assessing QOL needs, facilitating patients' understanding of disease status, and providing access to supportive care services. **Implications:** APRNs can develop a model of care to support patients completing clinical trials.

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In 2024, the American Society of Clinical Oncology (ASCO) released updated guidelines on palliative care for patients with cancer (Sanders et al., 2024). Based on a review of evidence and expert panel deliberation, the guidelines presented six recommendations. This included four recommendations reinforcing basic principles of referring oncology patients to interdisciplinary palliative care services and two recommendations related to specific oncology populations in need of enhanced attention for palliative care needs. These specific populations were those with hematologic malignancies and patients in early phase clinical trials. This paper reports on a pilot feasibility testing of an advanced practice registered nurse (APRN)-led intervention for improved care of patients completing early phase trials.

As summarized in the recent ASCO guidelines and other literature, patients on clinical trials face numerous physical and psychosocial concerns (Canzona et al., 2018; Cho et al., 2018; Finlay et al., 2009; Sanders et al., 2024). These include multiple symptoms associated with their advancing disease and treatments, and living with the uncertainty of experimental therapies from clinical trials. Advances in treatments mean patients often remain on disease-focused therapy much longer than in previous years. Survival trajectories and clinical trial participation are also accompanied by patient and family physical, psychosocial, and financial burdens such as living with the uncertainty of the disease and frequent travel and clinic visits for trial participation (Hlubocky et al., 2021; Kessler et al., 2014; Kimmelman, 2017; Kogan et al., 2022; Paluri et al., 2020; Rezash et al., 2020).

The 2024 ASCO guidelines' review of evidence reported a median survival for patients of only 5.7 to 10.7 months after completing a clinical trial. Yet literature (Ferrell et al., 2021; Kessler et al., 2014; Rezash et al., 2020) documents that phase I trial patients have very infrequently completed advanced care planning, received palliative care consultation, or had a documented goals-of-care discussion. Other literature has confirmed the supportive care needs of patients on clinical trials (Sedhom et al., 2021; Sedhom et al., 2020; Sun et al., 2014).

The authors' previous research in this area included testing a palliative care intervention in the phase I population. This National Cancer Institute (NCI)-supported study focused on the time period of patients' initial enrollment on a clinical trial through trial completion (*N* = 479; Ferrell et al., 2021). Key findings included the lack of planning for the transition in care after the trial, high symptom burden, repeat urgent care visits and hospitalizations, limited use of palliative care or other support services, and limited and late referrals to hospice.

One of the additional observations from the aforementioned study was that patients' needs actually increased beyond the trial completion as symptoms increased and their disease progressed. Patients struggled with the transition in care beyond the trial. This included many patients who had been initially treated at their community hospital oncology program but then transferred to a larger cancer center to access clinical trials. Once the trial was complete, they were uncertain if their community oncologist would resume care, if they would continue to go to the cancer center, or if there were no further therapies available and they would return to a primary care provider. Patients often voiced feeling "lost" as their clinical trials ended, and they were uncertain about their future care during this time of transition.

Based on the authors' previous study of patient needs while on clinical trials and a growing body of evidence regarding the needs of the phase I clinical trial population, the authors initiated a pilot project to develop an APRN-led support intervention to assist patients in the posttrial transition and to test the feasibility of the intervention.

METHODS

Sample and Setting

The setting was an NCI-designated Comprehensive Cancer Center in the western United States.

Aim

This pilot study was intended to develop and test the feasibility and initial outcomes of an intervention led by an APRN for patients with gastrointestinal (GI) tumors after completing a phase I trial. The pilot explored ways to help patients with the transition from care by the cancer center clinical trials team as they returned to their community clinicians or continued follow-up at the cancer center.

Objectives

The three study objectives were to (1) Develop the "Transitions" care plan intervention based on the authors' prior research to support patient quality of life (QOL), including symptom management, psychosocial support, and spiritual support, and transition in care after trial completion; (2) Test the feasibility of the intervention in a sample of patients with GI tumors completing a clinical trial; and (3) Evaluate the initial impact of the Transitions care plan intervention on improved care and QOL for patients completing clinical trials.

Conceptual Model

The development of the pilot intervention and initial testing were guided by the City of Hope QOL model (Ferrell, 1996). The QOL model includes four domains of physical, psychological, social, and spiritual well-being. It has been used extensively in oncology nursing. The model had also been used in the investigators' previous research with clinical trial patients. The domains capture the unique needs of this population and their physical needs such as symptom management, psychological concerns such as anxiety and depression as they face advancing disease and often limited treatment options, social well-being, including the need for family support and support services, and spiritual well-being as they face potential mortality.

Design

This was a single-group convenience sample with patients accrued at baseline when completing a phase I clinical trial and followed at 3 months and 6 months posttrial completion. Baseline data were considered the primary time point to assess the feasibility of accruing patients for this intervention and to describe their needs when transitioning off the clinical trial. The 3-month follow-up was the key outcome time point to assess the initial impact of the intervention. The 6-month follow-up provided an assessment of continued care and mortality. The study was approved by the center's Institutional Review Board. The sample size was selected as the number of available subjects during the pilot time frame and the projected accrual goal was met.

Procedures

Based on the authors' previous work, the Transitions care plan intervention was designed to include collaboration by an APRN and medical oncologist to assess patients' QOL needs and goals of care at trial completion and plan for transition beyond the trial. Procedures included the following.

(1) The APRN reviewed cases each week during the study accrual phase to identify patients who had been on a phase I trial for at least 1 month. In consultation with the medical oncologist, the APRN monitored their status to identify when patients might be completing a trial.

(2) The APRN invited the patient to participate in this pilot intervention and follow-up evaluation. Written consent was obtained from the patient.

(3) The APRN then reviewed the medical record and contacted the medical oncologist when it was anticipated that the patient would be completing the trial. The APRN gained information regarding the patient's disease status, prognosis, and the oncologist's plan for continued care. The APRN met with the patient to document a Transitions care plan for the patient with information about who would provide their continued care and recommendations for support services to address QOL concerns such as symptom management needs, hospice, palliative care, or care to be provided by a community oncologist or primary care provider. As advance care planning is also an important part of usual care, the intervention used the current institutional resources for advance care planning, such as completion of an advance directive.

The APRN determined if the patient had an advance directive and referred patients to the cancer center's online site for advance care planning forms such as the Provider Orders for Life-Sustaining Treatment (POLST) and other resources. This Transitions care plan was based on principles of palliative care such as assessment of the patient understanding of the disease, goals of care, symptom management, and holistic QOL concerns (National Consensus Project for Quality Palliative Care, 2018). The intervention was also based on oncology case management, such as clear planning on who will provide continued care and the support services that can be arranged to meet future needs, such as referrals to social work, palliative care, chaplaincy, hospice, and other support services (Case Management Society of America, 2024).

(4) The APRN created a written Transitions care plan, met with the patient to review the plan in collaboration with the medical oncologist as indicated, and assisted in referrals to palliative care, hospice, social work, or other support services.

Outcome Measures

Instruments included a demographic and treatment data tool; chart audit to document supportive care resources used; and the Functional Assessment of Cancer Therapy - General (FACT-G) QOL tool (Cella et al., 1993), which assesses QOL across domains including symptoms; the Psychological Distress Scale (Jacobsen et al., 2005); and the Functional Assessment of Chronic Illness Therapy - Spiritual Well-Being 12 Item Scale (FACIT-Sp-12; Bredle et al., 2011) tool, which assesses spiritual well-being. Each of these tools is widely used in oncology with well-established reliability and validity. Additionally, patients were invited to participate in an interview at the 3-month evaluation time point to provide qualitative data regarding their experience as a part of the feasibility testing and to gain their perspectives on the pilot intervention. The interviews were conducted by the APRN, recorded, and transcribed verbatim. The interview questions asked patients to share their understanding of their disease status, continued care, and support needed.

RESULTS

Demographic Data

Table 1 summarizes the sample demographics collected at baseline. The mean age of patients was 56 years, and 60% were male. Forty-three percent were non-Hispanic White. Other ethnicities included Hispanic (27%), Asian (22%), Native American (5%), and African American (3%). The patients were predominantly Catholic (41%). Colorectal cancers were most common. The mean time since diagnosis was 5.27 years. Eighty-seven percent had stage IV disease. Only 6 patients (16.2%) were receiving supportive care services.

Feasibility

The objective of establishing feasibility of the pilot intervention was evaluated based on the ability to accrue subjects to the study, collaboration between the APRN and MD to create the Transitions care plan, and patient participation in the teaching session and use of the Transitions care plan.

Overall, the investigators found the Transitions care plan process to be feasible with a high acceptability by patients and oncologists. The researchers considered the option of having the plan completed by the APRN together with the oncologist in a clinic visit but determined prior to initiation of the pilot that this would not be feasible due to the limited clinic time available for the oncologists. They also had considered a design in which the Transitions care plan would be completed by the clinical trials nurse familiar with the patient; however, this also was deemed unrealistic due to time constraints of these nurses. The use of an APRN, in this case, a nurse from the research team, was selected to simulate what might become a model that could be incorporated into APRN practice in the clinics. In most cases, completing the Transitions care plan and meeting with the patient for discussion took 30 minutes or less of the APRN's time.

Quality of Life

Table 2 presents QOL data as assessed by the FACT instrument at baseline. The FACT items are scored from 0 to 4. Items are transposed for analysis, with 0 as negative and 4 as positive outcomes. In the area of emotional well-being, patients rated their greatest concerns in the areas of "I am losing hope in my fight against the illness" (mean = 3.43) and "I am satisfied with how I am coping with my illness" (mean = 3.05). In the functional well-being scale, the greatest concerns were in "I have accepted my illness" (mean = 3.05) and "I am able to enjoy life" (mean = 2.92). The physical well-being scale measures symptoms and their impact. Nausea (mean = 3.16) and trouble meeting the needs of family (mean = 2.78) were the worst scored items. In the area of social well-being, patients overall reported positive support from family and friends, with the item related to sexuality rated low (mean = 1.52).

Spiritual Well-Being

The FACT QOL instruments include a separate tool to measure spiritual well-being, the FACIT tool, which is a 12-item scale with items rated as 0 = not at all to 4 = very much. The scale includes a broad array of items measuring varied aspects of spirituality and subscales of meaning, peace, and faith. Table 3 presents the FACIT data. The highest rated items were "I have a reason for living" (mean = 3.89) and "My life lacks meaning and purpose" (mean = 3.49). The lowest rated item was "My illness has strengthened my faith or spiritual beliefs" (mean = 2.41).

Distress

Psychological distress was measured using the single item Psychological Distress Thermometer. Distress is measured on a scale of 0 = no distress to 10 = a great deal of distress. The mean score was 3.35 at baseline.

QOL, FACIT, and Distress Follow-Up Data

Scores were compared in the baseline measures with follow-up at 3 months in order to evaluate the initial impact of the pilot intervention. One-way repeated analysis of variance (ANOVA) indicated no significant change over the 3 months in the scales. Clinically, the team observed that this initial period in the first months after phase I trial completion was stable. However, as described in the following sections, patients' statuses declined and there was high mortality in the subsequent months as diseases progressed.

Qualitative Interviews

To gain a more in-depth understanding of patient needs and experiences transitioning off their phase I clinical trial, interviews were conducted with patients at the completion of the 3-month survey, with 28 of the 37 subjects participating in an interview. The interviews were conducted by phone, on Zoom, or in person. The interviews were audio recorded and transcribed verbatim with content analysis completed by the principal investigator with extensive qualitative research experience. Themes were reviewed by the research nurse and by all authors. Using an interview guide, patients were asked to share their understanding of their disease status, continued care and treatment, support needed, and current priorities or goals. Themes and patient sample quotes are provided in Table 4.

The qualitative themes reflect the patients' focus on survival despite having late-stage disease. Patients often voiced their intent to "wait for another trial" or "buy time," avoiding the reality of their disease status and experience of continued treatment. The data also described the many QOL concerns, including symptoms of their disease or treatment, the impact on their family, and financial burden. Patients also described the support they were receiving from their faith. The qualitative data reinforced the unique needs of the clinical trial population, as patients generally had progressing disease and yet remained focused on further treatment.

Table 1. Demographic Data

	***N* (%)**
Age in years, mean (range)	56 (35–71)
Gender	
Male	22 (60)
Female	15 (40)
Ethnicity	
Non-Hispanic White	16 (43)
Hispanic	10 (27)
African American	1 (3)
Asian	8 (22)
Native American	2 (5)
Religious preference	
Catholic	15 (41)
Jewish	2 (5)
Protestant	10 (27)
Other	6 (14)
None	5 (13)
Type of cancer	
Colon/rectal/anal	24 (60)
Liver	6 (15)
Pancreatic	6 (15)
Bile duct	1 (3)
Time since cancer diagnosis in years, mean (range)	5.27 (1–24)
Stage of disease	
Stage I	2 (5)
Stage II	2 (5)
Stage III	1 (3)
Stage IV	32 (87)
Receiving supportive care services	
Yes	6 (16.2)
No	31 (83.8)

Table 2. Functional Assessment of Cancer Therapy - General (FACT-G) Scores

	Mean	SD
Emotional well-being		
I feel sad	2.70	1.19
I am satisfied with how I am coping with my illness	3.05	0.99
I am losing hope in my fight against the illness	3.43	0.93
I feel nervous	2.81	1.05
I worry about dying	2.62	1.28
I worry that my condition will get worse	2.00	1.22
Functional well-being		
I am able to work (include work at home)	2.41	1.52
My work (include work at home) is fulfilling	2.72	1.30
I am able to enjoy life	2.92	1.06
I have accepted my illness	3.05	0.97
I am sleeping well	2.59	1.19
I am enjoying the things I usually do for fun	2.62	1.30
I am content with the quality of my life right now	2.24	1.28
Physical well-being		
I have a lack of energy	2.14	1.18
I have nausea	3.16	1.04
Because of my physical condition, I have trouble meeting the needs of my family	2.78	1.23
I have pain	2.38	1.40
I am bothered by side effects of treatment	2.41	1.30
I feel ill	2.70	1.22
I am forced to spend time in bed	2.65	1.53
Social/family well-being		
I feel close to my friends	3.32	0.97
I get emotional support from my family	3.76	0.60
I get support from my friends	3.38	0.98
My family has accepted my illness	3.30	0.81
I am satisfied with family communication about my illness	3.43	0.73
I am satisfied with my sex life	1.52	1.29

Transitions Care Plan

The Transitions care plan form was completed by the APRN and documented patients' understanding of their disease status, symptoms, and plans for continued care. Table 5 presents the form with an example of a patient care plan. Table 6 presents analysis of the 27 patients with completed care plans. Ten patients did not have a completed care plan, generally because they felt too sick, went on hospice, chose treatment closer to home, or had continued on a clinical trial at the time of this pilot study ending. This attrition of 10 subjects was important data in considering the feasibility testing of this pilot and potential need to initiate the plan while patients were still on trial.

Chart Audit Data

The chart audit of the 37 patients at study completion revealed that patients received a variety of supportive services from social work (55.6%), physical therapy/occupational therapy (22.2%), nutrition (16.7%), or a pain management consultation (16.7%). On average, all patients had approximately two or more treatments consisting of either

Table 3. **Functional Assessment of Chronic Illness Therapy - Spiritual Well-Being 12 Item Scale (FACIT-Sp-12; 0 = not at all, 4= very much)**

	Mean	SD
I feel peace	2.57	.93
I have a reason for living	3.89	.39
My life has been productive	3.32	.91
I have trouble feeling peace of mind	2.76	.95
I feel a sense of purpose in my life	3.32	1.08
I am able to reach down deep into myself for comfort	2.97	.90
I feel a sense of harmony within myself	2.97	.80
My life lacks meaning and purpose	3.49	1.10
I find comfort in my faith or spiritual beliefs	3.00	.91
I find strength in my faith or spiritual beliefs	3.00	.91
My illness has strengthened my faith or spiritual beliefs	2.41	1.44
I know that whatever happens with my illness, things will be okay	2.86	1.06

chemotherapy (97.3%), surgery (67.6%), and/or radiation (27.0%). All but one patient had full code status (94.4%), with few having a living will, advance directives, POLST, or designated proxy decision maker (27.8%) or power of attorney (2.8%).

Twenty-one of 37 patients had a variety of unscheduled encounters for symptom management, with the highest percentage of encounters being for pain (57.1%), diarrhea (23.8%), and fever/infection (23.8%). On average, patients experienced two unscheduled encounters to manage symptoms. All admissions were symptom related. Symptoms included pain (*n* = 5), fever (*n* = 3), nausea/vomiting (*n* = 2), diarrhea (*n* = 2), or neurologic symptoms (*n* = 1). Chart audits were conducted at the conclusion of the project. Therefore, there was some variation in the length of time since trial completion, depending on when the patient was accrued to the study. At the pilot study completion, 10 patients had died, and 4 additional patients were enrolled in hospice.

DISCUSSION

This study developed and conducted initial testing of a Transitions care plan designed to facilitate the transition of patients beyond clinical trials. Swenne and colleagues (2024) conducted a scoping review of the integration of palliative care by primary care providers and oncology care. Their review identified 12 components of integrated care, including early identification of needs, education, communication, advance care planning, assessment and management of symptoms, coordination, multidisciplinary team meetings, involvement of informal caregivers and continuous quality improvement. The findings from this study were consistent with these patient needs.

Ulrich and colleagues (2021) published results of a qualitative study of patients who withdrew from a clinical trial. Similar to the qualitative data reported in this study, they reported themes of patient prognostic awareness, need for goals of care discussions, emotional coping, the burden of adverse effects, and the need for professional trust and support. This pilot study also reported themes of patients experiencing distress from uncertainty and feeling lost in the transition.

Other studies have reported data regarding health services used by clinical trial patients facing the end of life. Sedhom and colleagues (2021) reviewed care of 207 patients on phase I trials. Only 53% had goals-of-care discussions documented, 47% were referred to palliative care, and 41% had discussed hospice with their oncologist. Many studies have reported patient hesitancy to accept palliative care, as they believed it indicated they were giving up hope (Yang et al., 2023).

IMPLICATIONS FOR ADVANCED PRACTITIONERS

The results from the pilot study document some of the continued challenges in transitioning

Table 4. **Qualitative Themes**

Theme	Patient quote
Waiting for another trial	They gave me the option of hospice or one last shot at the traditional chemo. So, I took the one last shot at the traditional chemo. I'm waiting, I'm waiting for them to tell me when I start. Oh, it's been kind of a bumpy road. I just got off another clinical trial that we did not have any success with, so that's where we're at. Dr. P's working on two new clinical trials that are coming online...It's serious. We're out of options...but regular chemo and anything like that...is no long a viable option. So I am left with clinical trials.
Buying time	When I was first diagnosed, they were like, oh, we can buy you some more years. I asked him how the treatment was going to work, and he said I was not going to be cured and that it would probably give me like 10 months or, you know, something like that, or longer. I don't know if he meant life or what. Well, I guess we know what's coming subsequently and eventually, but when it comes, we're not quite sure. But in the meantime, we pretty much want to squeeze as much life as we can into that space of time, however long it is.
Continuous treatment	Stage four chemo, surgery, chemo, NED (no evidence of disease). Recurrence, chemo, surgery, chemo, trial. Chemo... Palliative chemo.
Effects of treatment	This immunotherapy knocked me out completely. 100%. I was bedridden for 2 months. I lost all my muscles. I lost a ton of weight...I was not capable of getting out of bed to go to the bathroom...I couldn't squeeze a ball...The tank was empty, the car wouldn't run...And I'm waking up during the night...It's definitely messed up my sleep cycle. I'm getting a lot more pain...from my stoma. But I'm walking around during the day feeling this horrible hangover feeling and...it's really awful every single day.
Avoidance	I did not want to fill one (advance directive) out. I know the comprehensive cancer center out here asked if I wanted to fill one out. I know several people asked if I wanted to fill one out. And I said no, because I'm not going to die. ...When I think about what's going on inside of my body and how I feel on a normal day, I feel like it's not that bad but I mean, I don't know. And like I said, I don't like to ask too many questions because I don't want to hear answers that I don't want to hear.
Impact on family	My husband is sitting right here, and he is going to have a tantrum. He hates when I say this, but I don't want to be a burden on the family. And so I was thinking if I did the chemo, the traditional chemo first and it doesn't work out and I go to hospice, I can make it past Christmas so everybody can have a holiday and not be put out. We have very open communication, so I let them [children] know everything, but without it being scary. They know...cancer's not good and that's scary. They watched my mother-in-law pass away from cancer. So it was really scary when I was diagnosed...I try to keep things light but I tell them everything...I'm trying to tell them like there's a plan...even though this is bad, there's still good things going on.
Spiritual support	...and my belief is if I can get it, God can take it, but it says His time is, it's not the way I want...But even in just the slow decreasing, I'm grateful that it is decreasing, not increasing. I got a lot to be thankful for. It's part of my life now. And until God says, that's it, you know? So I'm grateful to be able to go through it. And it's a process...it just challenges me in time...I'm grateful...So when I get home, I go to church and we have prayer.
Financial burden	To try to figure out something I could do to help pay for it, because traveling every 2 weeks...is really expensive. I didn't realize how expensive cancer was...And then I thought that they had said that the trial was going to reimburse for expenses. But then I submitted all that, but they came back and said they were just doing mileage...So that kind of sucked...Because even though it takes my insurance, there's still other payments and stuff and it's just very difficult on top of everything.
Quality of life	I think that my priority is quality of life...that I can still live kind of independently to a certain extent. You know, get up by myself, go to the bathroom by myself...That to me is the top priority. And the conversation really changed for me, after surgery I wanted quality of life before I wanted quantity...When I first was diagnosed, I didn't want to talk about it...because I couldn't process it. And then you start seeing the physical changes and it's like going through the stages of grief. It's like you're grieving your healthy self into this new self.
Survival	To get cured of this stuff. To be in remission for the rest of my life. Die with it, not from it. I want to be as happy, in a functional life,...find some normalcy within the craziness of my treatment. I want to try to live as much of a normal life as I can within my new normal...But my new normal has been this for almost 3 years...I have survived 100% of my worst days. You know, I kind of equate myself to the phoenix. I feel like I'm always rising, have to rebuild. You know, you fall, you rebuild, you fall and you just keep rebuilding.

Table 5. **Plan of Care for Patients Transitioning Off Clinical Trials**

Date: December 2, 2023

Name: Marco R.

The Current Status of Your Cancer
Your doctor has explained that your stomach cancer has continued to grow and there was no reduction in the cancer from the medication you received on the clinical trial. The latest scans also show increased spread of the cancer into your liver.

Your Needs for Support and Plans for Receiving Care Needed
You have shared that your greatest concerns are to get your pain under control as you want to travel to visit your parents who live out of state one last time and your need to work with your son who will be taking over your business. You need your symptoms to be controlled but you don't want to be too sedated.

Your Symptoms and Plan for Management

Symptom	**Plan**
Pain (averaging 6-8/10), worse on movement	You have long-acting oxycodone and short-acting morphine ordered for pain but you haven't been taking these on a schedule. We have reviewed how to get these medications on a regular schedule. You have a new pain in your abdomen that the doctor thinks may be related to the cancer spreading to your liver. We are referring you for a consultation by our palliative care service to evaluate your pain and develop a plan.
Nausea	You think that your nausea is much better now that you have completed chemotherapy but we have reviewed your nausea medications (ondansetron) that can be used if you have any nausea.
Numbness in hands and feet	You are developing some numbness in your hands and feet that you think is getting worse since you started on the clinical trial. The palliative care team will also assess this and come up with a plan.

Advance Care Plan

_____ Complete

__X__ Not completed but plan for completion: Proxy decision maker and advance directive
You have not completed an advance directive. You shared that you have avoided doing this as you thought it might upset your wife and also that you didn't want your doctor to think you are giving up hope. We talked today about how important it is to have these decisions in order. Our social worker is meeting with you today to go over these forms to assist you and your wife.

Plan of Continued Care

_____ City of Hope

__X__ Other Provider
You have shared today that since you won't be on the trial any longer and the doctor has shared that your cancer is growing, that you will go back to the doctor who is much closer to your home as the drive in is becoming very difficult. We will be sending that doctor a summary of your treatment and also the current plans for managing your symptoms. Our palliative care team will also share their recommendations with that doctor.

Table 6. **Analysis of Plan of Care for Transition Off Clinical Trial (*N* = 27)**

	N
Understanding of the current status of the cancer	
Continued treatment is intended to keep cancer from progressing	7
No current treatment but waiting for another clinical trial or chemotherapy	7
Disease is stable	6
Disease is progressing	6
There are no other options	4
Hope to continue chemotherapy but balancing the need to manage side effects	3
Unaware of next steps/options	2
No further chemotherapy but receiving palliative radiation	2
Needs for support and plans for receiving care	
Social work referral to support spouse/family	6
Pain management consultation	5
Child life referral to support children	3
Social work or psychologist referral for emotions from "coming off the trial"	3
Need referral to hospice	3
Help to arrange for care when moving to another state	3
Need more nursing assistant level care	3
Spiritual care support	3
Legacy/How to leave a legacy for children or family	2
Help at home to assist with personal care and meals	2
Palliative care referral for support/concerns about pain and dying	2
Physical therapy referral	1
Help in coordinating care and appointments	1
Nutrition consult	1
Home care to help with total parenteral nutrition and peripherally inserted central catheter line	1
Symptoms	
Pain	15
GI distress/constipation/colitis/abdominal cramping/diarrhea	15
Nausea/vomiting	11
Fatigue	8
Weight loss/loss of appetite	5
Neuropathy	4
Sleep	2
Depression/hopelessness	2
Anxiety	2
Edema	2
Dyspnea	1
Itching	1
Dry eyes	1
Advance care plan	
Has ACP and in EMR	10
No ACP	10
Has an ACP but it is not in the EMR	4
Plan for continued care after clinical trial	
Continue at City of Hope	15
Community physician	3
Will be moving to be near family out of state/but no physician or plan	3
Moving out of state to seek clinical trials available there	3
Hospice	3

patients from clinical trials. Feasibility was assessed with some positive findings, as patients were able to be accrued to the study and interviews confirmed their needs for support. Some patients ended trial participation abruptly as symptoms progressed, when they no longer met the trial requirement, or if they became too ill. There also remains a desire by patients to continue treatment, even when benefit is unlikely. As in previous studies, mortality rates were high in this study. The qualitative data captured the many emotions and the experiences of patients as they were impacted by their late-stage disease, symptoms, and awareness of their mortality. The study also illustrates the profound struggle of patients on clinical trials as they hope for new options for disease-focused care and prolonged life while also facing the reality of diminishing treatment options and often death within months of trial completion.

There were some benefits seen in this pilot intervention. The APRN-led intervention provided a link between the oncologist, patient, and supportive care resources. The APRN was able to assess the status of symptom management, facilitate referral to supportive care services in the cancer center and to hospice. The APRN also worked closely with the clinical trial nurses who are the key source of support for patients on trials, offering vital connections to services needed and transition in care.

Consistent with extensive research on advance care planning, these patients benefitted from the additional education and support to complete advance directives, input these into the medical record, and have them communicated to clinicians. The APRN also provided emotional support for these patients and families during this difficult time in the care transition. Compared to the authors' previous study of patients on clinical trials, this pilot study did increase referrals to social work, which was seen as vital in helping patients and their families.

CONCLUSION

There is an increasing amount of literature documenting the unmet supportive care needs of patients on clinical trials (Sanders et al., 2024; Ulrich & Grady, 2019). While there is strong agreement on the importance of clinical trials to advance cancer treatment (Yang et al., 2023), obstacles remain in making supportive care the norm for these patients (Anderson et al., 2022). APRNs remain central in the times of transition by patients, but as Canzona and colleagues (2018) wrote in their article on nurses' attempts to help patients and families manage the transition from oncology to comfort care, challenges include a lack of clear communication, unclear goals of care, and need for emotional support. Other authors have cited similar needs for support by family caregivers of patients on phase I trials, especially during times of transition (Kessler et al., 2014; Kogan et al., 2022; Rezash et al., 2020). While evidence is limited, investigators have demonstrated the ability for palliative care to provide improved symptom management, QOL and family caregiver support, and also to enhance the ability of patients to participate and complete clinical trials (Treasure et al., 2021).

This pilot study demonstrated the need for supportive care integration in the clinical trials population to address unmet needs and to facilitate this important time of transition in the cancer care trajectory. A transition plan or other models of care may help to address QOL concerns, relieve symptoms, avoid unnecessary hospital or urgent care admissions, and ensure that patients receive palliative or hospice care at the end of life. This is a difficult time with significant staff shortages and diminishing health system resources. Thus, new models of care must recognize challenges and limitations. Future research can test models of care and help create a new standard of care for this important population. ●

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Disclosure

The authors have no conflicts of interest to disclose.

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