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Patient Perspectives on Participation in the ENABLE II Randomized Controlled Trial of a Concurrent Oncology Palliative Care Intervention: Benefits and Burdens

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Abstract

Background—ENABLE (Educate, Nurture, Advise Before Life Ends) II was one of the first randomized controlled trials (RCTs) examining the effects of a concurrent oncology palliative care intervention on quality of life, mood, and symptom control for advanced cancer patients and their caregivers. However, little is known about how participants experience early palliative care and the benefits and burdens of participating in a palliative care clinical trial.

Aim—To gain a deeper understanding of participants' perspectives about the intervention and palliative care trial participation.

Design—A qualitative descriptive study using thematic analysis to determine benefits and burdens of a new palliative care intervention and trial participation.

Setting/Participants—Of the 72 participants who were alive when the study commenced, 53 agreed to complete an in-depth, semi-structured interview regarding the ENABLE II intervention and clinical trial participation.

Results—Participants' perceptions of intervention benefits were represented by four themes: enhanced problem-solving skills, better coping, feeling empowered, and feeling supported or reassured. Three themes related to trial participation: helping future patients and contributing to science, gaining insight through completion of questionnaires, and trial/intervention aspects to improve.

Conclusions—The benefits of the intervention and the positive aspects of trial participation outweighed trial "burdens". This study raises additional important questions relevant to future trial design and intervention development: when should a palliative care intervention be initiated and

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what aspects of self-care and healthy living should be offered in addition to palliative content for advanced cancer patients when they are feeling well?

Keywords

Qualitative Study; Randomized Controlled Trial; Palliative Care; Intervention study

Introduction

There is general agreement about the need for research to support the evidence-base of palliative care.(1-3) However, conducting research with seriously ill patients has generated controversy due to concerns about the burdens of participation in vulnerable patients and the potential for harm if patients are 'labeled' as terminal.(3-5) In 1990, the World Health Organization (WHO) proposed a concurrent care model that introduced palliative care at the time of diagnosis of serious illness, with increasing support as disease progressed.(6) While "up-streaming" care made intuitive sense, little was known about how patients might respond to this approach. Might patients experience negative emotions or "harm" if they were identified as eligible for palliative care? Would the burdens of research participation outweigh the benefits?

ENABLE (Educate, Nurture, Advise Before Life Ends) II was one of the first randomized controlled trials (RCTs) to examine the quality of life, mood, and symptom control effects of concurrent palliative care on for patients with advanced cancer and their caregivers compared to usual care.(7, 8) In addition to the primary trial outcomes, we were interested in participants' perspectives on the intervention itself and in research participation. Qualitative methods have been recommended as an integral part of intervention research so that complex phenomenon will be better understood.(2, 9, 10) Therefore, near the conclusion of the ENABLE II RCT, we invited all intervention and usual care participants to describe their experiences with the intervention and research participation. The goal of this qualitative adjunct study was to gain perspectives about the intervention and trial participation not obtainable through the quantitative study measures. (2, 11, 12) Consolidated criteria for reporting qualitative research (COREQ) were used to prepare this report. (13)

Methods

Study Design

This qualitative interview study of participants' views of a new palliative care intervention and study participation that was informed by qualitative thematic analysis methods recommended for examining complex interventions.(11, 14-16) The parent RCT methods and outcomes have been reported elsewhere (7, 8, 17, 18). Briefly, between November 2003-May 2007, three hundred and twenty-two patients with newly diagnosed advanced or recurrent lung, gastrointestinal (GI), genitourinary, or breast cancer were enrolled in the parent RCT (intervention n= 161; usual care n=161). When the interview study commenced in July of 2007, 72 RCT participants were alive (35 intervention, 37 usual care). Fifty-three (27 intervention, 26 usual care) participants agreed to be interviewed. Six participants either could not be contacted or declined participation and 13 could not complete the interview due to illness. One interview was lost due to technical issues resulting in 52 interviews available for analysis. The institutional review boards of Dartmouth College and the Veterans Affairs Medical Center (VAMC), White River Junction, Vermont approved the study protocol.

Intervention

The intervention, (described in detail elsewhere (7, 19)) was based on the WHO continuum of care (6) and Wagner's Chronic Illness Care (CIC) Model (20). ENABLE employed a case management, psycho-educational multicomponent intervention to enhance patient activation, self-management and empowerment skills. Advanced practice nurses with palliative care training conducted four telephone-based educational sessions guided by the "Charting your Course: An Intervention for People and Families Living with Cancer" workbook. The workbook contained four chapters: 1) problem-solving, 2) communication with the healthcare team and social support, 3) symptom management, 4) advanced care planning, and an appendix of supportive care resources. (The workbook is available at http://cancer.dartmouth.edu/palliative_care/other_resources.html). Following the four structured sessions, the advanced practice nurse continued at least monthly telephone contact to assess the need for referral to appropriate resources.

The advanced practice nurse began telephone contacts with an overall assessment by administering the Distress Thermometer, an 11-point rating scale (0-10) recommended by the National Comprehensive Cancer Network (21, 22). If distress was 3 or greater, the nurse explored the sources of distress and encouraged the participant to apply a problem-solving approach to address his or her issues. Then they covered the material scheduled for that session. Additionally, the intervention participants were invited to participate in a monthly shared medical appointment (SMA) (23, 24) with a palliative care physician and nurse practitioner. The SMA was designed to provide an opportunity for face-to-face interaction and in-depth discussions about symptom management problems or related issues (e.g., insurance, social services). Usual care participants were allowed to use all oncology and supportive services without restrictions.

All participants were asked to complete questionnaires via mail at enrollment, 1 month after enrollment, and every 3 months until the participant died or study completion (December 2007). Questionnaires included: the Functional Assessment of Chronic Illness Therapy for Palliative Care, a 46-item tool measuring physical, emotional, social and functional well-being in addition to concerns relevant to persons with life threatening illness (25); a modified Edmonton Symptom Assessment Scale which assessed 9 symptoms of pain, activity, nausea, depression, anxiety, drowsiness, appetite, sense of well-being, and shortness of breath(26); and the Center for Epidemiological Studies Depression Scale which assessed depressive symptoms.(27)

Interview Guide and Data Collection

The interview guide was developed by the investigators with input from the literature, (5, 11) was pilot tested with two non-participating advanced cancer patients and revised. The interview began with a general question about the participants' cancer diagnosis experience and care and then explored topics including: physical symptoms, decision-making, the care team, communication, use of supportive care resources, and experiences with study participation (e.g. timing of enrollment, completing questionnaires, and views about components of the intervention). Two trained research coordinators not involved in the parent RCT conducted all study interviews by telephone. The principal investigator (PI) (MB) provided extensive interviewer training via a manual, role-play, and practice interviews to ensure high quality and reliable interview skills. The training manual included resources on how to ask questions and an overview of the study aims. The interviewers each conducted 2 digitally recorded mock interviews with non-study cancer patients to pilot test the interview guide. The PI provided immediate feedback to the interviewer to improve questioning skills. The interview digital recordings were immediately downloaded onto a secure computer file. The PI reviewed each recording to debrief and provide timely

feedback on interviewing skills. Intervention participant interviews lasted on average 33 minutes (range 13-63 minutes) and usual care participant interviews averaged 28 minutes (range 9-48 minutes).

Data Analysis

Data analysis followed standard procedures of descriptive thematic analysis. (11, 14-16) Two transcriptionists prepared verbatim transcripts from the digital recordings. Research assistants or the PI reviewed all interviews for accuracy by comparing the digital recording to the transcripts. The transcripts were then entered into Atlas.ti qualitative software (v.5.0 Scientific Software Development, Berlin, Germany). The PI listened to the recordings and read each transcript multiple times. Data analysis was ongoing throughout data collection. Two ENABLE team members (KL, MB) and a qualitative research consultant independently coded 5 interviews and then met over a series of months to reach consensus on emerging codes and to develop a codebook. Two trained research assistants then coded the remaining transcripts using this codebook. The PI verified coding accuracy by independently coding five randomly chosen transcripts and comparing them for consistency. Coded data were clustered according to themes and categories. Only themes specific to the intervention and trial participation are presented here.

Results

Demographic characteristics for the RCT and interview participants are compared in Table 1. RCT and interview participants' characteristics were similar except that the interview sample had fewer patients with GI malignancies, spent fewer days in the hospital in the 3 months prior to baseline assessment, and had overall longer participation.

RCT participation rates are presented in Table 2. Interview participants completed an average of 7 outcome assessments (range 0-15, $sd = 4.4$) and 13 nurse interventionist phone sessions prior to being interviewed (range 4-35, $sd = 8.5$). Only nine interview participants had ever attended an SMA for a median of 2.5 sessions (range 1 to 24). Of the 53 participants interviewed, 12 died within 4 to 28 weeks of being interviewed (7 intervention, 5 usual care). One male interviewee withdrew from usual care arm of the RCT citing too much burden.

Thematic Results

Table 3 illustrates themes and exemplar quotes of study participants' experiences with the intervention and trial participation. Codes specific to the intervention clustered into four main themes: 1) enhanced problem-solving skills, 2) better coping, 3) feeling empowered and 4) feeling supported and reassured. Codes related to trial participation clustered into three themes: 1) helping future patients and contributing to science (altruism), 2) completing questionnaires provided insights into condition and emotions, and 3) trial/intervention aspects to improve.

Enhanced problem-solving

Intervention participants learned how to handle situations differently through the "Charting Your Course" problem-solving module: "Even if I'd already done the things, it gave you suggestions as to other ways to do it..." (P19 Intervention; Gastrointestinal (GI)). Participants found the problem-solving technique helpful (see Table 3) in making problems more manageable or tackling a small part of a problem related to their illness, symptoms, or family/health care team communication: "I think that that's probably the most, one of the most helpful things, and it does help you to break it down if you're having trouble figuring out where the problem is." (P17 Intervention; GI). A participant noted that they learned how

to tackle situations “logically” to determine what needed to happen next. Another participant stated that the problem-solving technique helped them to communicate with their caregivers regarding the direction of their care. Participants stated that they had more information about who to contact or how to complete paperwork to help them address their problems.

Better Coping

Participants noted that they were better able to cope with uncertainty and to deal more directly with concerns about the future. The cancer diagnosis experience was new to them and most related that they were uncertain how to cope with this new situation: “I thought it... might help me out...if I had some concerns about... what would be happening down the road.” (P18 Intervention; GI). One participant noted that the intervention helped them to identify their support system. Participants described feeling more comfortable with what to expect and what not to expect as their disease progressed. One participant noted that the intervention helped them “keep things in perspective...just kind of press forward with hope.” (P21 Intervention; GI).

Feeling Empowered

Intervention participants felt more empowered and they changed from a passive to a more active role in their health care and in their dealings with family and friends. One participant stated: “I’ve become more willing to say, you know, ‘I’m not able to do this, or I’m not able to do that because I’m too tired or too fatigued...’ Whereas before, I might have said, ‘Oh, okay, I’ll go ahead and do it anyway.’” (P23 Intervention; Lung). Another participant described how they felt proactive and were planning ahead if they should lose capacity due to illness: “It was the information on how to get your healthcare if you can’t say what to do. You know I was like, ‘see, we’ve got to take care of things’” (P4 Intervention; Breast).

Feeling Supported, Reassured, and Hopeful

Intervention participants felt supported and reassured as a result of their telephone sessions with their nurse educators. This regular contact between clinic appointments was especially helpful when participants were not feeling well: “...the phone calls. Especially in the beginning when I felt really lousy from the chemo...I think it’s kind of made everything just a little easier.” (P4 Intervention; Breast) The participants found the regular phone contact with the nurse to be reassuring and allowed them to have conversations about sensitive topics. This was described by two different participants, “Well, it’s added support for me, given me a chance to discuss certain parts of some problems that I might have had; just kind of reassuring” (P24 Intervention; Genitourinary (GU)) and “I feel comfortable telling (the nurse educator) if I don’t feel well and I feel comfortable with her if I’m scared ...”. (P3 Intervention; Breast). The contact and attention from the nurse educator also seemed to foster feelings of hopefulness. One participant stated: “it kind of gave me hope that, ‘Hey I’m not going to fall over in six months.’ ‘Hey (the nurse) couldn’t have bothered with taking down information and working with me if I’m just going to go down the road in six months and go bleep (die)’. So I felt like, okay, ‘Hey this is good!’”. (P4 Intervention; Breast).

Themes Related to Trial Participation

Helping future patients and contributing to science (altruism)—Most intervention and usual care participants expressed that study participation increased their overall well-being due to “giving to others.” This altruistic benefit is exemplified in the following: “I feel if I can help one person that gets cancer; the whole journey has been worth it.” (P4 Intervention; Breast). Two usual care participants also commented about altruistic motivations: “Well, if what I’ve gone through can help anyone else, I don’t mind” (P31 Control; Breast) and “I just hope that my responses might help those that come along, you

know, the newly diagnosed ones.” (P28 Control; Breast). Several participants described wanting to help other patients by increasing health care providers and scientists understanding about the patients’ illness experience. One participant noted “I figure the more knowledge you've got, the better job you can do with your patients”. (P6 Intervention; Breast).

Completing questionnaires provided insights into condition and emotions—

Participants felt that completing the questionnaire regarding our primary outcomes provided them with a regular self-assessment and valuable insights into their condition and emotions. An intervention participant stated: “They (the questionnaires) make me think, ‘How have I felt? How am I feeling?’ Because I have a tendency, maybe all people who are sick do, to kind of just cruise along saying, ‘I’m fine’.” (P4 Intervention; Breast). Usual care participants also appeared to receive a similar benefit as evidenced by one who stated: “It gave me food for thought, it gave me more insight into perhaps what was really bothering me...some of the questions would bring to light, maybe some of the things I had been feeling, but didn't realize it until I had to answer.” (P30 Control; Breast) Completing the questionnaires also raised their awareness of how their condition changed over time: “It also made me aware of any little changes....the answer might be, well, maybe a little different this time, or changed, which made me more aware of myself.” (P46 Control; Breast).

Trial/Intervention Aspects to Improve

Trial participation was not described as particularly ‘burdensome’; however some downsides or disappointments were identified. Table 3 provides exemplar quotes of four specific issues. A control patient expressed disappointment about not being randomized to the intervention group and therefore did not get the added support that may have been available through the trial. The SMAs were meant to provide opportunities for in-person assessment by the palliative care physician and advance practice nurse and group discussion of common issues. These meetings were not well-attended, even when a call-in option was created; participants identified travel distance, timing of the SMAs, and being too sick to travel as reasons for lack of attendance. The participants who did attend, found the lack of participation disappointing: “The biggest disappointment was going into the group meetings and feeling as if ... the energy wasn't there ... So, I didn't feel like it was as helpful as it could have been.” (P14 Intervention; GI).

Intervention participants who were asymptomatic also found less benefit from the intervention, though they commented on the potential future value for themselves or others who were having symptoms: “I think it probably would have been helpful, but my symptoms never developed, so, I think when you are not feeling threatened, you tend to not do that stuff (e.g. activities in the curriculum related to symptom control, etc.).” (P1 Intervention; Breast) Similarly participants who were feeling relatively well or preferred to use denial or avoidance to cope with their illness didn't want to feel like “...a *patient every day*” (P14 Intervention; GI) and preferred to have less contact with medical professionals.

Discussion

The qualitative component of the ENABLE II palliative care RCT sought to explore participants’ experiences with the intervention and trial participation in order to inform future palliative care trials. Intervention participants comments grouped into themes that provide insights about the mechanisms of the intervention that may have contributed to improved quality of life and mood. These include: feeling supported, acquiring new skills and tools to enhance problem solving and coping, and feeling empowered to actively participate in their health care choices. These characteristics are consistent with the interventions’ underlying conceptual model -Wagner's Chronic Illness Care (CIC) Model

(20). According to the CIC improved problem solving, empowerment and behavioral activation are elements that can lead to a “productive clinical interaction” and ultimately positive clinical outcomes. While we did not use a specific quantitative measure of these concepts, such as the Patient Assessment of Chronic Illness Care (PACIC), (28) to see if these elements mediated the change in quality of life and mood,(8) our results are suggestive of such a mechanism. Hence, we have included the PACIC in our in progress RCT (RO1-NR011871-01) to test this hypothesis.

The intervention participants found the ongoing relationship with the nurse educator informative, supportive, and reassuring. The benefits of an individualized relationship are reflected in other studies in which participants report good communication and supportive ongoing personal contact as beneficial. (29) Participants felt supported in their decision-making throughout the course of their illness. Studies of patients with other chronic illnesses have identified that improved relationships with clinicians resulted in participants reporting a more substantial role in shaping their health care.(30) Feelings of hopefulness, that seemed to result from nurse contact and trial participation, contradict the concern voiced by many clinicians that introducing palliative care earlier in the disease course would diminish hope. (31)

Participants’ experiences with trial participation were mostly positive. Other palliative care study participants have also described altruistic benefits.(29, 32-34) Although many patients hope that they will personally benefit (even in Phase I studies focused on establishing safety), altruism remains a significant motivation. Participants in our study and in studies of non-cancer participants (29, 33, 35, 36) report nearly unanimous agreement that a primary motivation for study participation was to help future patients or to help scientists and clinicians to better understand their experience.

An important reason for conducting this qualitative study was to gain a better perspective about potential trial participation burdens for patients with serious illness. Participants in this study did not describe participation as ‘burdensome’ per se, but rather described some inconveniences or disappointments. For example poor SMA attendance was disappointing to some participants. In retrospect the poor attendance should not have been surprising given our rural environment (37, 38) and our prior experience.(19) In the original ENABLE demonstration project the intervention was conducted entirely in person in a group setting. (19) Long travel distances to the medical center and the decreased energy of participants resulted in reduced participation in some in-person intervention components and considerable support by telephone. This provided the rationale for conducting the ENABLE RCT primarily by telephone. The purpose of the SMA in the RCT was to maintain a forum for in-person and group experiences; however participants did not perceive a need for this and identified the same barriers to participation: travel distance, timing, and being too sick to travel. This important finding guided our decision to forgo this component in our current RCT and reinforced the importance of developing creative strategies, including telemedicine and community-based palliative care, to increase access for seriously ill patients in a rural environment.(37, 38)

In addition, we were highly sensitive to the burden of regularly collecting multiple self-reports in patients with limited reserves. However, both intervention and usual care participants, identified questionnaire completion as beneficial as it stimulated and enhanced self-assessment. The benefits of self-reflection was also found in a study of women with newly diagnosed breast cancer.(39) A few participants felt that completing questionnaires and trial participation caused sadness as they were reminded of their illness and a likely foreshortened future. Other studies participants have also commented that study

questionnaires were ‘depressing’ or difficult to answer due to their ‘black/white’ choices. (40)

Some topics were notable for their lack of prominence. Few patients mentioned the symptom management and advance care planning intervention components. This is not surprising in that many participants were asymptomatic during the time of the study. More than 40% of the participants had some form of advance directive prior to study enrollment. Therefore these topics may not have been as salient for participants interviewed.

Despite the benefits of a qualitative RCT adjunct study, a few limitations are notable. The qualitative study and RCT participants had similar baseline characteristics, but important differences may not have been measured. Interviewed subjects had participated in the study almost twice as long (26 months) as the average RCT participant (14 months). The views of participants who withdrew from the study (29 intervention; 28 control) are not reflected, and this selection bias may have resulted in a more favorable overall response to study participation. While views of RCT participants who died prior to the commencement of this study are not reflected, 12 interview study participants died within 4-28 weeks of being interviewed (range 22-215 days, mean = 104, *sd* = 62 days) providing a perspective from patients who are near the end of life. This study focused on an intervention to address the needs of a predominantly rural palliative care population. The lack of ethnic diversity in rural New Hampshire and Vermont may limit the generalizability of these results to a more ethnically diverse, urban sample. Strengths of this study include the large number of qualitative interviews analyzed (n=52) that provided a substantial breadth of study participation experiences.

Conclusions

This study has important implications for future palliative care research. First, concerns about negative responses of patients to early introduction of palliative care seem unfounded. However, “early”, asymptomatic patients may derive fewer benefits from an intervention addressing issues of more serious illness. The in-progress ENABLE III RCT is designed to examine the optimal timing of “early” palliative care. Second, this intervention focused on preparing for serious illness and preventing crises, however we have now added content on self-care and healthy living to benefit asymptomatic participants. Lastly, while investigators must remain diligent about minimizing burdens and risks, these findings suggest that early palliative care trial participation appears to be more beneficial than burdensome.

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Table 1

Demographic characteristics

	RCT Sample N=322	Qualitative Interview Sample N=53[*]	
	N (%)	N (%)	p-value^{**}
Intervention	161 (50)	27 (51)	1.00
Age, mean (SD)	65.0 (11.2)	63.3 (11.1)	0.22
Gender			
Male	187 (58.1)	25 (47.2)	0.09
Marital Status			
Never married	27 (8.4)	3 (5.7)	0.86
Married or living with partner	221 (68.6)	38 (71.7)	
Divorced or Separated	42 (13.1)	6 (11.3)	
Widowed	32 (9.9)	6 (11.3)	
Education			
Less than high school	37 (11.5)	4 (7.6)	0.27
High school	157 (48.8)	29 (54.7)	
College	81 (25.2)	19 (35.9)	
Missing	47 (14.6)	1 (1.9)	
Ethnicity			
White	275 (85.4)	51 (96.2)	1.00
Black	0	0	
Hispanic	0	0	
Other	2 (0.6)	0	
Missing	45 (14.0)	2 (3.8)	
Employment status			
Employed	63 (19.6)	15 (28.3)	0.20
Retired	162 (50.3)	26 (49.1)	
Not employed	93 (28.9)	12 (22.6)	
Missing	4 (1.2)	0 (0)	
Rural	181 (56.2)	29 (54.7)	0.88
NCCC, Enrollment Site	222 (68.9)	39 (73.6)	0.52
Trial participation, months	14.63 (12.75)	26.61(13.59)	<0.0001
Primary disease site			
Gastrointestinal	133 (41.3)	14 (26.4)	<0.01
Genito-urinary	39 (12.1)	9 (17.0)	
Breast	33 (10.3)	12 (22.6)	
Lung	117 (36.3)	18 (34.0)	
Enrolled Caregiver	193 (59.9)	32 (60.4)	1.00
Referral to hospice	10 (3.1)	0 (0)	0.38

	RCT Sample N=322	Qualitative Interview Sample N=53 [*]	
	N (%)	N (%)	p-value ^{**}
Referral to palliative care	93 (28.9)	15 (28.3)	1.00
With advance directives			
Living will	145 (45.0)	22 (41.5)	0.65
Durable power of attorney	146 (45.3)	23 (43.4)	0.76
DNR	23 (7.1)	2 (3.8)	0.39
Days in hospital over past three months	3.0 (5.2)	1.1 (2.3)	<0.01
Days in ICU over past three months	0.03 (0.25)	0.06 (0.3)	0.48
Emergency room visits over past three months	0.34 (0.78)	0.26 (0.8)	0.45
FACIT-PAL	131.9 (24.5)	138.0 (23.9)	0.05
ESAS	284.3 (151.1)	234.6 (154.1)	0.01
CESD	12.9 (8.7)	11.3 (8.7)	0.16
KPS	77.3 (12.1)	81.3 (9.4)	0.01

NCCC- Norris Cotton Cancer Center

FACIT-Pal- the Functional Assessment of Chronic Illness Therapy for Palliative Care.

Scores range from 0 to 184, with higher scores indicating better quality of life.

ESAS - Edmonton Symptom Assessment Scale. Scores range from 0 to 900, with higher scores indicating greater symptom intensity.

CES-D - Center for Epidemiological Studies Depression Scale. Scores range from 0 to 60, with higher scores indicating more depressed mood.

KPS – Karnofsky Performance Scale. Scores range from 0 to 100 in 10-point increments, with higher scores indicating better health and performance of daily activities.

^{*} Note: Survey data was available from the 53 participants that were interviewed, however due to technical issues interview data were only available from 52 participants.

^{**} Tests of distributions are between parent study 269 subjects and 53 interview study subjects from t-test for continuous variables or Fisher's Exact test for categorical variables.

Table 2
Interview Participant Outcome Assessment and Intervention Session Completion Rates

	Full interview sample (N = 53)		Intervention participants (n = 27)		Usual care participants (n = 26)	
	Range	Mean (sd)	Range	Mean (sd)	Range	Mean (sd)
Outcome assessments completed	0-15	7.4 (4.4)	1-14	6.5 (4.1)	0-15	8.3 (4.7)
Outcome assessments missed	0-3	0.6 (0.9)	0-3	0.8 (1.0)	0-3	0.3 (0.7)
Nurse sessions completed	N/A	N/A	4-35	12.9 (8.5)	N/A	N/A

Table 3

Themes Related to Intervention and Trial Participation

Theme	Exemplar quote
Themes Related to Intervention Participation	
Enhanced problem-solving	"I think the steps in...decision making and communication...it was most helpful dealing with my husband and the problem I was having with, you know, juggling between him and an oncologist, and what my needs were and how needy he was...." (P14 Intervention; GI)
Better coping	"I thought, number one, there's a listing in the back (of "Charting your Course") that gives you a lot of outside organizations that can help or give you information....Also, some of the things to help you think through, for example, if you're diagnosed with an end stage illness, what should you be thinking about, what do you think you ought to be doing right now in preparation?" (P23 Intervention; Lung)
Feeling empowered	"She's (nurse educator) given me that nudge when I've had some problems. I'll go back to the doctor and talk with him or something like that." (P24 Intervention; GU)
Feeling supported, reassured, and hopeful	"It's been a supportive mechanism, you know, because, for example, when the nurse and I would talk on the phone, she knew what was going on with me. It wasn't like I had to explain everything, so that was very supportive." (P23 Intervention; Lung)
Themes Related to Trial Participation	
Helping future patients and contributing to science (altruism)	"I believe that when somebody, for example in my situation, finds out you have a terminal disease, yeah, it's rocky and it's emotional, but my thought was, if the study would help other people, that's a good thing." (P23 Intervention; Lung) "Well, I guess my attitude is that, um, knowledge is power. The more that the scientists and the doctors know, the sooner there is going to be a cure, or there is going to be a treatment that is going to prolong somebody's life." (P3 Intervention; Breast)
Completing questionnaires provided insights into condition and emotions	"I felt in some way, like somebody was hearing my individual situation. It, it was interesting to fill it out. It was sort of like, you know, instead of keeping a diary... 'How has your last week actually been?' Well, it's sort of nice to sit down and think about it." (P14 Intervention; GI)
Trial/Intervention Aspects to Improve	Control patient disappointment: <i>"I was hoping that it would give me some support and, uh, I don't really feel that it has."</i> (P28 Control; Breast) Shared medical appointment not well-attended: <i>"I was the only one there though...I'm interested in joining groups like that, or participating in groups like that, it tends to, particularly the groups in around here, a lot of people don't show up...If it doesn't seem like there's enough people, it doesn't really make sense to me to, you know, to participate"</i> (P5 Intervention; Breast) Didn't apply to me: <i>"Actually up until a couple of months ago, a lot of the stuff that was in the book that I was given, it wasn't even appropriate. I mean, it wasn't necessary for me...at first I couldn't relate to a lot of the stuff."</i> (P17 Intervention; GI) Reminded me about illness: <i>"I did sort of let go for a while on participation, and it was more because I was having too much fun, and I didn't want to be a patient that day. I don't want to be a patient every day of my life. And, so the less time I have with the medical profession, the more I feel like a normal person."</i> (P14 Intervention; GI)