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Phase 2 pilot study of Pathfinders: a psychosocial intervention for cancer patients

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Abstract

Purpose—Pathfinders is a multi-faceted psychosocial care program for cancer patients; it was developed in community oncology and adapted to the academic oncology setting. This prospective, single-arm, phase 2 pilot study examined the acceptability and feasibility of Pathfinders for women with metastatic breast cancer.

Methods—Over 3 months, participants completed patient-reported surveys including the Patient Care Monitor (PCM, review of systems), Functional Assessment of Chronic Illness Therapy—Breast Cancer (FACT-B), Self Efficacy, and a single-item survey asking patients whether the

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program was helpful to them. A technology-based data collection system was used to capture electronic patient-reported outcomes at point of care, report symptoms in real time to clinicians, and collect warehouse data to provide a detailed longitudinal picture of the patient experience when receiving Pathfinders.

Results—Participants ($n=50$) were: mean age 51 (SD 11); 76% white, 20% black; 74% married; 50% college degree. Forty-two ($n=42$) patients completed baseline and 3-month assessments. Statistically significant improvements (all $P<0.05$) occurred in PCM subscales for Distress (mean [SE]=−3.42 [1.21]), Despair (−4.53 [1.56]), and Quality of Life (2.88 [0.97]), and the FACT-B Emotional Wellbeing subscale (2.07 [0.46]). Of the 29 participants asked if Pathfinders was helpful, 27 (93%) responded positively and two did not respond. Other instruments measuring symptoms, quality of life, and self-efficacy showed improvement.

Conclusions—In a phase 2 pilot study, Pathfinders was helpful to patients and is feasible in an academic medical center. Follow-up data collected at the 3-month assessment suggest that the program impacts various psychological outcomes, notably distress and despair.

Keywords

Patient-reported outcomes; Psychosocial oncology; Quality of life; Neoplasms; Distress

Introduction

A substantial evidence base confirms that cancer patients experience significant psychosocial symptoms. Psychological distress, including anxiety, depression, and changes in mood, affects over 35% of all patients with cancer [1]. For example, studies have found that depression diminishes cancer patients' quality of life (QOL), and that greater severity of depression is associated with a faster rate of disease progression and a greater severity of other cancer-related symptoms, particularly pain [2, 3]. In addition, studies of cancer patients meeting criteria for post-traumatic stress symptomatology have been also documented, though incidence rates vary [4].

Currently, the primary mode of delivering psychosocial care to cancer patients is through adjunctive programs (e.g., psychotherapy, support groups, and psycho-education). These services are typically provided by social workers, counselors, and chaplains in parallel with medical care, but with providers often uninformed. Patient navigator models attempt to bridge communications between the patient, family, and medical team; however, it is difficult to determine the benefits given their diversity in content. Likewise, limited rigorous research has been conducted on cancer patient support programs for reasons including lack of resources, inter-program variability, and difficulty identifying key outcome variables. Specific psychological interventions such as cognitive-behavioral therapy and psycho-education (e.g., self-care information provided to patients post-surgery) have been studied in adult cancer patients and survivors. Several meta-analyses have looked at the effectiveness of these interventions but results have been varied, igniting a debate over their effectiveness [5, 6]. A review of the literature in June 2008 yielded no rigorous studies on any comprehensive psychosocial intervention that was *fully integrated into the context of medical care*.

Pathfinders is a psychosocial program designed for cancer patients at all disease stages. As shown in Fig. 1, the program seeks to effect “personal recovery” by identification and activation of the individual's innate strengths through both therapist-led and self-guided inquiry.

A manual guides the implementation, but the intervention is tailored to address patient-specific needs. Pathfinders work in close concert with clinical providers to facilitate patient/provider communication and attend to their patients' non-medical needs. The program has served patients at two community sites in Colorado since 2000 and at an academic medical center in North Carolina since 2006.

This paper presents the initial results of a pilot study (i.e., phase 2 clinical trial) of Pathfinders among metastatic breast cancer patients at Duke University Medical Center, which was conducted in parallel with program implementation. The purpose of the pilot was to determine whether this model of psychosocial care is acceptable to patients and feasible in the academic medical center setting. A further objective was to determine the best outcome(s) upon which to design a larger, well-powered, randomized controlled (i.e., phase 3) trial.

Methods

Study design

This was a prospective, single-arm, phase 2 pilot study conducted at one institution (Duke University Medical Center, Durham, NC, USA) from January 2006 to June 2008. Participants received the Pathfinders intervention over a 6-month period, interfacing with a Pathfinder at baseline and approximately monthly thereafter. The primary outcome was acceptability, assessed by the proportion of patients reporting that the program helped them. Secondary outcomes included QOL, distress, despair, functionality, spirituality, fatigue, self-efficacy, and symptoms. A 3-month analysis was planned to determine if the study should continue and to direct research next steps; results are presented here. The Duke Institutional Review Board approved the study, and informed consent was obtained from all study participants.

The study was designed to ensure that the Pathfinders intervention could be delivered as seamlessly as possible (i.e., with little intrusion from the research team). Data were collected in a clinic using paper-based and electronic versions of validated assessments; electronic surveys were delivered by e/Tablet (wireless, tablet-style, personal computers used in the clinical waiting area), an efficient and unobtrusive system coordinated as a part of the normal clinical care environment [7].

Participants and setting

The original protocol stipulated enrollment of 48 eligible patients to ensure that at least 40 patients would complete at least the 3-month assessment. A sample size of 40 provided >80% power to differentiate between a helpfulness rate of 80% and 95% at the 3-month assessment with a one-sample binomial test ($P=0.05$). Due to higher-than-anticipated attrition, the sample size goal was raised to 55 patients.

Eligible participants were: adult; female; diagnosed with metastatic breast cancer; receiving chemotherapy, intravenous immunotherapy, or intravenous bisphosphonate therapy; expected to live ≥ 6 months; able/willing to travel to clinic at least every 4 weeks; English-literate; and consenting.

Intervention

Each patient met individually with a "Pathfinder", a trained and licensed social worker. Psychosocial services provided by the Pathfinder included cognitive restructuring, mind/body technique instruction, and self-care and end-of-life planning. While following a standardized program manual, the Pathfinder customized the intervention to the specific

circumstances, needs, and characteristics of the individual patient. It was intended that these newly developed and enhanced skills would help patients navigate through potential setbacks of cancer and its treatment and maintain personal well-being through survivorship or end of life. The Pathfinder met with the participant at least monthly for up to 6 months and communicated regularly with the oncology team.

Data collection and instruments

Patient-reported outcomes were collected electronically (via e/Tablets [7]) and using paper-based surveys. Electronic instruments included: (1) Functional Assessment of Cancer Therapy—Breast Cancer Scale (FACT-B) [8, 9], a 44-item self-report instrument, measuring QOL in breast cancer patients; (2) Functional Assessment of Chronic Illness Therapy—Fatigue Scale (FACIT-F) [10], a 13-item survey, measuring fatigue; (3) M.D. Anderson Symptom Inventory (MDASI) [11], a 19-item survey with two subscales, measuring severity of symptoms and their interference with daily living; and (4) Patient Care Monitor 2™ (PCM, originally called Cancer Care Monitor; Supportive Oncology Services, Inc.) [12], an 86-item review of systems, generating seven subscales including a global QOL score.

Paper-based surveys included: (1) the helpfulness question; (2) Self Efficacy Scale [13]; (3) FACIT—Spiritual Well-Being Scale (FACIT-Sp) [14]; (4) Life Orientation Test—Revised [15]; and (5) Brief COPE Survey [16].

Statistical analysis

Statistical analyses focused on data collected between baseline and 3-month assessments. The primary foci were the (1) acceptability and feasibility of Pathfinders at an academic medical center and (2) strength of other outcomes as potential endpoints for a larger study of this psychosocial model. Feasibility and acceptability was assessed through the helpfulness question and estimated with an exact 95% binomial confidence interval. A paired *t* test was used to assess changes in subscale scores between baseline and the 3-month assessment with a step-down Bonferroni approach to adjust significance levels given the multiple analyses. Among study participants completing baseline and 3-month assessments, the proportion of participants with a score >3 was reported for individual symptoms (PCM) at baseline and 3 months. For symptoms that improved by >10%, McNemar's test was used to determine if there were differences in the proportion of patients with a symptom score >3 at baseline and at 3 months. Bonferroni corrections were used to adjust significance levels. All analyses were conducted using SAS Version 9.1. A two-sided significance level of 0.05 was used for all statistical tests.

Results

Participants ($n=50$) were: mean age 51 (SD, 12); 76% white, 20% black; 74% married; 50% college degree (Table 1). The study population had advanced breast cancer; attrition at 3 months was 16% (four died, one withdrew, and three did not have assessment data available due to rapidly progressive illness). Of participants completing the 3-month assessment ($n=42$), 29 (69%) were asked the Pathfinders helpfulness question due to difficulties with administration of paper surveys, and of those, 27 (93%) indicated that Pathfinders was helpful and two did not respond.

As shown in Table 2, significant improvements (all $P<0.05$) in QOL and distress scores from baseline to 3 months were achieved despite participants' advanced and progressive disease: PCM Distress (mean change [SE]= -3.42 [1.21]); PCM Despair (-4.53 [1.56]); PCM Quality of Life (2.88 [0.97]); and FACT-G Emotional Wellbeing (2.07 [0.46]). While

statistically non-significant, other measures (e.g., FACT-B, FACIT-F, and MDASI Interference) showed a trend towards improvement. Finally, Table 3 highlights symptoms that showed a >10% change in prevalence, with change in prevalence of nervousness significant at $P<0.05$.

Discussion

This phase 2 pilot study examined the short-term impact of the Pathfinders program on QOL-related outcomes. Before preparing for a randomized controlled trial, it was necessary to determine whether the academic medical setting could accommodate this type of psychosocial program or whether there was the potential for positive impact. Results indicated that most (93%) study participants found the intervention helpful, and the high retention rate coupled with continuous referrals from physicians affirmed the program's acceptability.

Certain outcomes (e.g., distress and despair) evidenced improvement despite the progress of disease. Recent studies have examined trends in QOL-related scores in patients nearing end of life. One prospective, longitudinal study in an advanced cancer cohort ($n=67$) reported steady decline in FACT-G scores over the 6 months preceding death, accelerated decline in the last 2–3 months, and dramatic increase in psychological symptoms in the last month [17]. In contrast, a study among breast cancer survivors in China reported significant improvement over time in many outcomes. However, even among these long-term survivors, certain aspects of QOL either failed to improve or worsened (e.g., emotions and social support) [18]. Because we lack survival data on our cohort, we were unable to directly relate these results to our population; however, they demonstrate a pattern that suggests the need for psychosocial intervention for advanced cancer patients nearing death.

Many participants experienced significant improvement in self-efficacy, which is defined as having confidence to carry out a behavior necessary to reach a desired goal. Individuals with high self-efficacy for health behaviors are more likely to exercise, seek preventive care, halt negative behaviors (e.g., smoking), and report better health status [19, 20]. Given self-efficacy's potential function as a mediator of Pathfinders' effect on outcomes, future analyses will examine the correlation between improvement in various patient resources (e.g., self-efficacy and coping) and QOL-related outcomes.

While its primary focus is on psychosocial outcomes, Pathfinders may contribute to alleviation of other symptoms and side effects of cancer and cancer treatment. For example, participants reported a >10% decrease in prevalence between baseline and 3 months on fatigue. The mechanism of such changes is unclear, although likely relates to the close relationship with psychological distress. Efforts to evaluate various inflammatory pathways as a potential mechanism are also underway.

This study had several limitations, including the lack of a control group. This was intended to be an exploratory phase 2 pilot study to establish feasibility and determine the potential for meaningful outcomes; based upon these results, a phase 3 trial is planned. A second limitation is that the pilot study included only women with metastatic breast cancer; hence, results may not generalize to men or to other cancer diagnoses. Third, this pilot study relied heavily on a single provider of the intervention (i.e., one Pathfinder), although three additional Pathfinders have been trained over the course of the study. Finally, while an attempt was made to ensure that study visits were timed per protocol, the realities of usual clinical care for sick patients translated to visits that were frequently off-schedule.

Despite these limitations, data gained in this pilot study led to clarification of design elements to be used in a randomized controlled trial that will rigorously test Pathfinders.

Appropriate endpoints include distress and QOL measures; in addition, we are considering a model in which self-efficacy functions as a mediator of the intervention's effect. A confirmatory trial will have a broader scope, enrolling four cancer types (breast, lung, colorectal cancer, and ovarian) and both genders, which will help establish the generalizability of results.

In this preliminary study, we found that Pathfinders, a novel and multi-faceted psychosocial program, could be adapted to an academic center and was deemed helpful by patients with metastatic breast cancer. Follow-up data collected at the 3-month assessment suggest that the program impacts various psychological outcomes, notably distress and despair, and provides justification for further study in a more diverse cancer sample.

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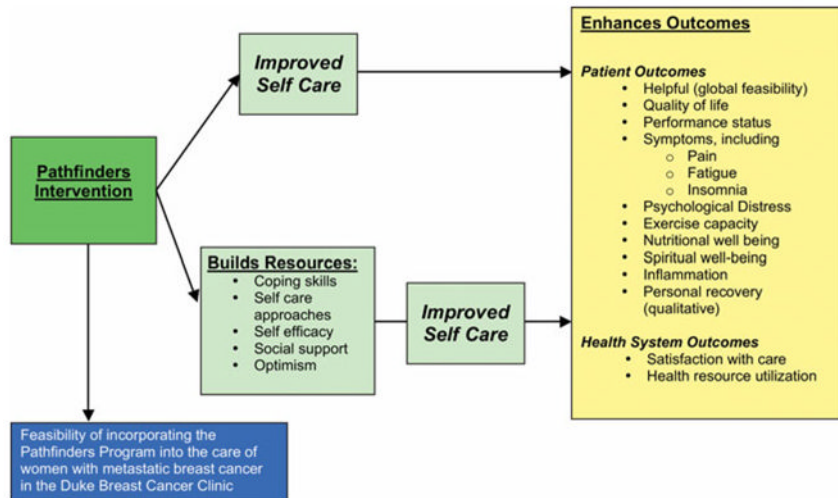


Fig. 1. Conceptual model guiding the Pathfinders pilot study. Quantitative data on helpfulness, quality of life, symptoms, psychological distress, self-efficacy, and spirituality are presented here. Other information such as coping, self-care, exercise, nutrition, inflammation, and health service utilization will be presented separately

Table 1

Demographics of the study sample

	Number or mean (SD)	Percent or [range]
Gender		
Female	50	100%
Age in years		
At study enrollment	51.2 (11.5)	[31–79]
At diagnosis	47.3 (11.5)	[26–79]
Marital status		
Married	37	74%
Not married	13	26%
Education		
Less than bachelor's degree	25	50%
Bachelor's degree and above	25	50%
Race/ethnicity		
White, Caucasian	38	76%
Black or African-American	10	20%
Korean	1	2%
Other	1	2%
Cancer stage at diagnosis		
Stage 1	6	12%
Stage 2	19	38%
Stage 3	5	10%
Stage 4	12	24%
Missing	8	16%
Current extent of disease		
Distant metastases	50	100%

Table 2

Change in subscale scores from baseline

Scale: subscale	Number	Baseline mean (SE)	Mean change from baseline mean (SE), at 3 months	Meaning of direction of change ^a
PCM: general physical symptoms	36	26.23 (2.59)	-3.58 (1.84)	Improvement
PCM: treatment side effects	36	12.5 (1.36)	-0.92 (1.52)	
PCM: <i>distress</i>	36	11.36 (1.82)	-3.42 (1.21)*	<i>Improvement</i>
PCM: <i>despair</i>	36	11.53 (2.68)	-4.53 (1.56)*	<i>Improvement</i>
PCM: impaired performance	30	12.73 (2.17)	-1.03 (1.61)	Improvement
PCM: impaired ambulation	35	4.49 (1.11)	-1.31 (0.84)	Improvement
PCM: <i>quality of life</i>	30	-13.52 (1.85)	2.88 (0.97)*	<i>Improvement</i>
FACT-G: physical	36	16.99 (1.07)	1.73 (0.74)	Improvement
FACT-G: social	34	20.72 (0.96)	0.3 (0.57)	
FACT-G: <i>emotional</i>	36	15.56 (0.81)	2.07 (0.46)*	<i>Improvement</i>
FACT-G: functional	35	15.34 (1.13)	0.07 (0.72)	
FACT-B	40	22.81 (0.79)	1.69 (0.75)	Improvement
FACIT-Fatigue	39	25.67 (1.93)	2.91 (1.19)	Improvement
FACIT-Spirituality: meaning/peace	25	21.97 (1.61)	1.95 (0.99)	Improvement
FACIT-Spirituality: faith	25	12.24 (0.84)	-0.04 (0.57)	
MDASI: symptom severity	41	2.67 (0.3)	-0.17 (0.22)	
MDASI: interference	41	3.67 (0.45)	-0.73 (0.32)	Improvement
Self Efficacy: other	25	58.04 (3.78)	4.23 (2.91)	Improvement
Self Efficacy: pain	24	61.19 (4.85)	3.1 (4.22)	Improvement
Self Efficacy: functioning	24	62.64 (4.76)	4.58 (3.88)	Improvement
Self Efficacy: overall	24	59.18 (4.29)	3.94 (3.19)	Improvement

Italics indicate statistically significant improvement

PCM Patient Care Monitor, FACT-G/-B Functional Assessment of Cancer Therapy—General/Breast, FACIT Functional Assessment of Chronic Illness Therapy, MDASI M.D. Anderson Symptom Inventory, SE standard error

* $P < 0.05$ after step-down Bonferroni adjustment

^a Survey instruments may reflect improvement by increasing or decreasing scores. The implications of the change are presented here

Table 3

Change in selected symptoms from baseline, as reported on the Patient Care Monitor Instrument

System	Symptom	Change from baseline at 3 months		
		N	Percent with score >3 at baseline	Percent with score >3 at 3 months
Constitutional	Weight loss	36	<i>19</i>	8
	Weight gain	33	24	21
	Fatigue (tiredness)	35	66	49
Endocrine	Reduced sexual enjoyment, interest, or performance	34	41	29
Gastrointestinal	Nausea (queasy feeling)	35	20	11
	Decrease in appetite	36	17	6
	Increase in appetite	35	9	9
Psychiatric	Feeling I would be better off dead ^a	36	8	3
	Feeling hopeless ^a	36	22	11
	Nervous, tense, anxious ^b	36	47	22*
	Feeling helpless	36	25	19
	Lost interest in pleasurable activities ^a	36	25	14
	Feeling guilty ^a	36	25	11
	Lost interest in people ^a	36	14	11
	Worry ^b	36	44	33
	Crying/feeling like crying ^b	36	28	17
	Sad (depressed) ^b	36	33	17
Feeling worthless ^a	36	22	3	

Italics indicate meaningful improvement with >10% change

* $P < 0.05$ after step-down Bonferroni adjustment^a Patient Care Monitor Despair subscale item^b Patient Care Monitor Distress subscale item