

# IMPACT OF A PSYCHOSOCIAL INTERVENTION ON PERFORMANCE STATUS AND COPING

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## BACKGROUND

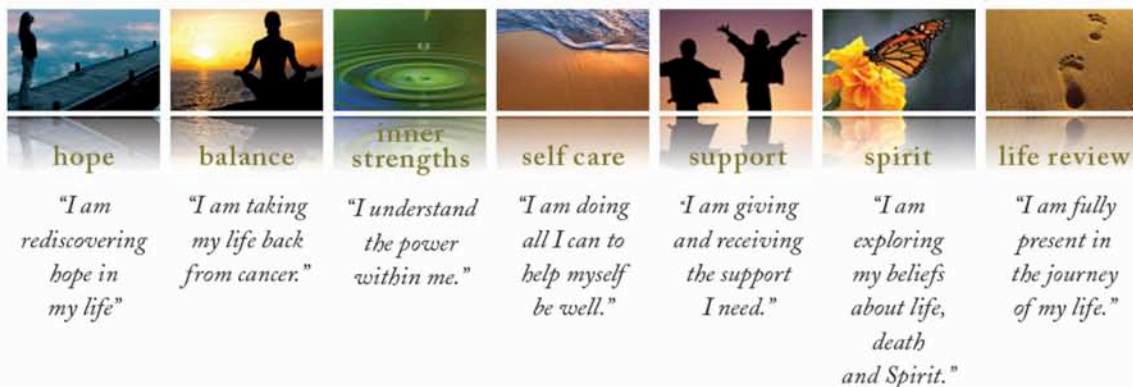
- ❖ Psychosocial distress is a critical cancer comorbidity; new interventions are needed.
- ❖ Psychosocial health services enable patients, their families, and health care providers to:
  - Make optimal use of healthcare resources
  - Manage the psychological/behavioral and social aspects of illness and its consequences
  - Take steps to promote better health
- ❖ Pathfinders began in 2003 in community oncology (Aspen Valley Hospital, Aspen CO).
- ❖ Pathfinders is a standardized program of comprehensive psychosocial support fully integrated with clinical care.
- ❖ Key components of Pathfinders:
  - Patient navigation and advocacy
  - Individualized psychotherapy/counseling
  - Coping skills training
  - Mind/body techniques (e.g., visualization)
  - Guidance on healthy lifestyle (e.g., diet, nutrition)

## OBJECTIVES

1. To determine the impact of Pathfinders on psychosocial symptoms experienced by advanced breast cancer patients.
2. To examine the durability over time of Pathfinders' impact on psychosocial symptoms, as patients' disease worsens.
3. To explore the impact of Pathfinders on other measures of potential impact including fatigue and quality of life.

Figure 1: Principal themes of the Pathfinders program

## The Seven Pillars of Personal Recovery



# METHODS

## OVERVIEW OF DESIGN

This was a prospective, single arm, pilot study, enrolling metastatic breast cancer patients with prognosis  $\geq 6$  months survival. 55 participants enrolled; 5 were unable to participate and were excluded from analyses, resulting in a total sample of 50. These analyses reflect data collected from January 2007 through December 2008.

## STUDY PARTICIPANTS

Eligible patients were:

- Adults  $\geq 18$  years old
- Diagnosed with metastatic breast cancer and expected to live  $\geq 6$  months
- Receiving cancer care at the Duke Breast clinic and receiving intravenous agent for cancer therapy (e.g. chemotherapy or bisphosphonates)
- Able and willing to return to clinic every 3 to 4 weeks
- Able to speak and read English
- Willing to provide informed consent

## SETTING

Duke University Medical Center (Durham, NC, USA)

## MEASURES

- Collected by electronic patient-reported data system at minimally 5 timepoints over 6 months:
  - Patient Care Monitor (PCM) - a validated review of symptoms and quality of life assessment inventory (Fortner et al, J Pain Symptom Manage 2003)
  - Functional Assessment of Cancer Therapy- Breast (FACT-B)
  - MD Anderson Symptom Inventory (MDASI)
  - Functional Assessment of Chronic Illness Therapy- Fatigue (FACIT-F)
- Collected by paper survey, at baseline, 3 and 6 months:
  - Self Efficacy Scale
  - FACIT- Spirituality scale

Figure 2: Conceptual model

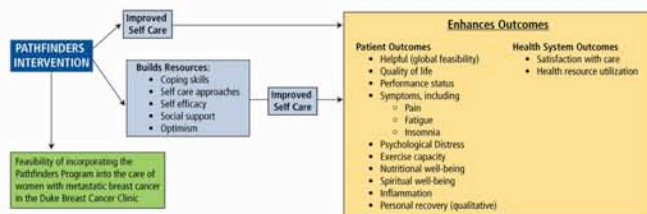


Table 1: Demographics and Clinical Variable

	N	%
<b>Gender</b>		
Female	50	100
<b>Age in years (mean, range)</b>		
At study enrollment	51.2 (11.5)	31-79
At diagnosis	46 (11.5)	25-79
<b>Marital status</b>		
Not married	13	26
Married	37	74
<b>Race/ethnicity</b>		
Black, African American	10	20
White, Caucasian	38	76
Other	2	4
<b>Education</b>		
Less than Bachelor's degree	25	50
Bachelor's degree and above	25	50
<b>ECOG</b>		
0	5	10
1	28	56
2 & 3	9	18
Missing	8	16

Table 2: Response to Pathfinders Helpfulness Question

Has Pathfinders been helpful to you?*	3 Month N (%)	6 Month N (%)
Yes	27 (93%)	18 (95%)
Missing	2 (7%)	1 (5%)

\*Although 42 participants completed the 3-month assessment, only 29 (69%) participants were asked the Pathfinders helpfulness question at the 3-month assessment. Twenty seven of these 29 (93%; 95% CI: 77%, 99%) participants indicated that Pathfinders was helpful, while 2 provided no response. A total of 33 patients completed the 6-month assessment, but only 19 (58%) participants were asked the Pathfinders helpfulness question at the 6 month assessment. Eighteen of these 19 (95%, 95% CI: 74%, 100%) participants indicated that Pathfinders was helpful, while 1 provided no response. Paper surveys were generally only given at visits 1, 3, and 6 which may or may not have corresponded to a 3 month or 6 month analysis timepoint. This may explain this significant amount of missing data.

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# RESULTS

**Table 3: Change in subscale scores from baseline**

Scale/Subscale	Change from baseline at 3 months				Change from baseline at 6 months			
	N	Baseline Mean (SE)	Change Mean (SE)	T-test p-value	N	Baseline Mean (SE)	Change Mean (SE)	T-test p-value
PCM General Physical Symptoms	36	26.23 (2.59)	-3.58 (1.84)	0.0600	28	25.42 (2.93)	-3.85 (2.48)	0.1322*
PCM Treatment Side Effects	36	12.5 (1.36)	-0.92 (1.52)	0.5472	28	11.4 (1.55)	-1.89 (1.75)	0.2903
PCM Distress	36	11.36 (1.82)	<b>-3.42 (1.21)</b>	<b>0.0078**</b>	28	10.57 (2.13)	<b>-4.11 (1.17)</b>	<b>0.0015**</b>
PCM Despair	36	11.53 (2.68)	<b>-4.53 (1.56)</b>	<b>0.0062**</b>	28	12.71 (3.36)	<b>-6.93 (2.71)</b>	<b>0.0163</b>
PCM Impaired Performance	30	12.73 (2.17)	-1.03 (1.61)	0.5249	25	11.8 (2.43)	0.48 (1.82)	0.7942
PCM Impaired Ambulation	35	4.49 (1.11)	-1.31 (0.84)	0.1278	27	4.33 (1.32)	0.07 (1.13)	0.9481
PCM Quality of Life	30	-13.52 (1.85)	<b>2.88 (0.97)</b>	<b>0.0058**</b>	25	-12.58 (2.11)	2.66 (1.45)	<b>0.0786</b>
FACT-G Physical	36	16.99 (1.07)	<b>1.73 (0.74)</b>	<b>0.0260</b>	28	17.31 (1.09)	-0.06 (1.31)	0.9641
FACT-G Social	34	20.72 (0.96)	0.3 (0.57)	0.6001	28	20.74 (1.03)	0.83 (0.9)	0.3644
FACT-G Emotional	36	15.56 (0.81)	<b>2.07 (0.46)</b>	<b>&lt;.0001**</b>	28	15.68 (0.91)	<b>1.75 (0.71)</b>	<b>0.0198</b>
FACT-G Functional	35	15.34 (1.13)	0.07 (0.72)	0.9220	28	14.25 (1.17)	1.36 (1.02)	0.1962
FACT-B	40	22.81 (0.79)	1.69 (0.75)	<b>0.0299</b>	30	22.84 (0.96)	0.66 (0.82)	0.4310
FACIT-Fatigue	39	25.67 (1.93)	2.91 (1.19)	<b>0.0197</b>	32	26.59 (2.01)	1.29 (1.54)	0.4072
FACIT-Sp Meaning/Peace	25	21.97 (1.61)	1.95 (0.99)	0.0604	21	22.2 (1.66)	2.18 (1.05)	0.0513
FACIT-Sp Faith	25	12.24 (0.84)	-0.04 (0.57)	0.9449	21	12.67 (0.78)	0.14 (0.49)	0.7755
MDASI Symptom Severity	41	2.67 (0.3)	-0.17 (0.22)	0.4387	32	2.74 (0.34)	0 (0.32)	0.9962
MDASI Interference	41	3.67 (0.45)	<b>-0.73 (0.32)</b>	<b>0.0299*</b>	32	3.57 (0.48)	-0.43 (0.51)	0.4045
Self Efficacy Other	25	58.04 (3.78)	4.23 (2.91)	0.1588	21	56.51 (3.95)	7.46 (3.27)	<b>0.0337</b>
Self Efficacy Pain	24	61.19 (4.85)	3.1 (4.22)	0.4704	18	56.83 (5.49)	3.65 (3.44)	0.3034
Self Efficacy Functioning	24	62.64 (4.76)	4.58 (3.88)	0.2501	20	57.5 (6.06)	6 (4.63)	0.2106
Self Efficacy Total	25	59.18 (4.29)	3.94 (3.19)	0.2286	19	55.45 (4.96)	5.96 (3.11)	0.0714

\*Indicates a significant difference on the unadjusted T test (<0.05), and a Bonferroni adjusted p value of <0.1

\*\*Indicates a significant difference on the unadjusted T test (<0.05), and a Bonferroni adjusted p value of <0.05.

**Bold Blue highlighting** indicates significant differences (p<0.05)

**Green highlighting** indicates scales/subscales that although not statistically significant, demonstrate trends of improved quality of life, reduction of symptoms, and improved coping skills

**O) Annual Meeting, Orlando, FL, May 29 - June 2, 2009**

## RESULTS *continued*

**Table 4: Selected concerns from the Patient Care Monitor (PCM)**

System / Symptom	Change from baseline at 3 months				Change from baseline at 6 months			
	N	% with score >3 at baseline	% with score >3 at 3 months	McNemar's exact p-value	N	% with score >3 at baseline	% with score >3 at 6 months	McNemar's exact p-value
<b>Psychiatric</b>								
Crying/feeling like crying <sup>b</sup>	36	28	17	0.2891	28	25	11	0.125
Feeling guilty <sup>a</sup>	36	25	11	0.0625	28	25	7	0.0625
Feeling helpless <sup>a</sup>	36	25	19		28	25	14	0.4531
Feeling hopeless <sup>a</sup>	36	22	11	0.2891	28	21	7	0.125
Feeling I would be better off dead <sup>a</sup>	36	8	3		28	11	4	
Feeling worthless <sup>a</sup>	36	22	3	0.0156	28	29	11	0.125
Lost interest in people <sup>a</sup>	36	14	11		28	18	7	0.25
Lost interest in pleasurable activities <sup>a</sup>	36	25	14	0.2891	28	29	14	0.2891
Nervous, tense, anxious <sup>b</sup>	36	47	22	0.0039**	28	43	25	0.0625
Sad (depressed) <sup>b</sup>	36	33	17	0.0703	28	29	11	0.0625
Worry <sup>b</sup>	36	44	33	0.2188	28	43	29	0.2188

<sup>a</sup>PCM Despair subscale item

<sup>b</sup>PCM Distress subscale item

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## CONCLUSIONS

- ❖ Patients unanimously find Pathfinders helpful.
- ❖ Pathfinders had a positive effect on key psychosocial and QOL outcomes, especially distress and despair.
- ❖ Improvements were seen despite the advanced stage of illness in the study cohort, with worsening symptoms and progressive disease.

## FUTURE DIRECTIONS

Follow-on studies will expand the Pathfinders model to other cancer types, and ultimately lead to a randomized controlled trial (RCT). The RCT will include both genders from a broader oncology population, build a longitudinal data set, and enable additional analyses.

The cost-effectiveness of this psychosocial program, and its impact on clinical flow and providers, are also being explored.



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