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## Brief Report: Correlates of Quality of Life-related Outcomes in Breast Cancer Patients Participating in the Pathfinders Pilot Study

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### Abstract

**Objective**—In a pilot study, participation in the Pathfinders program was associated with reductions in distress and despair and improvements in quality of life (QOL) among advanced breast cancer patients. This paper explores the relationship between psychosocial resources invoked through the Pathfinders intervention and outcomes.

**Methods**—Advanced breast cancer patients were enrolled in a prospective, single-arm, pilot study of the Pathfinders psychosocial program. Participants met at least monthly with a licensed clinical social worker who administered the Pathfinders intervention, which focused on strengthening adaptive coping skills, identifying inner strengths, and developing a self-care plan. Longitudinal assessments over 6 months used validated instruments to assess changes in Pathfinders targets (coping, social support, self-efficacy, spirituality, optimism) and outcomes (distress, despair, QOL, fatigue). Multiple linear regression models examined the joint effect of average changes in target subscales on average outcome changes, adjusted for baseline outcome scores and patient characteristics.

**Results**—Participants (n=44) were: mean age 51 (SD, 12), 20% non-Caucasian, 50% college degree, 75% married. Improvements in active coping skills, self-efficacy and spiritual meaning/peace significantly correlated with an improvement in despair after adjustment for demographic characteristics (all  $P < 0.05$ ). Improvements in social support significantly correlated with positive changes in distress ( $P < 0.05$ ). Gains in learned optimism independently correlated with an increase in overall QOL ( $P < 0.01$ ).

**Conclusions**—In this pilot assessment, changes in pre-defined Pathfinders targets such as coping skills, social support, self-efficacy, spirituality and optimism correlated with improvements in patient-reported outcomes.

## Keywords

cancer; oncology; quality of life; psychosocial; coping; intervention

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## Introduction

Cancer patients have substantial unmet psychosocial needs, as detailed in an Institute of Medicine (IOM) report on the psychological, social, and behavioral impacts of a cancer history, and their association with physical health across the cancer trajectory including survivorship [1]. In alignment with the IOM's proposed strategy, the Pathfinders program was designed by licensed clinical social workers as a strengths-based coping skills model. The program integrates psychosocial assessment and care for cancer patients through the guidance of a program manual, which outlines the use of tools and techniques (e.g., cognitive restructuring, guided imagery) to bolster the patient's resilience.

A conceptual model of the Pathfinders program (based on stress and coping [2] and social cognitive [3] theories) is presented in Figure 1. To assess the impact of Pathfinders and whether the program merited further study, we conducted a Phase II pilot study using the evaluation framework (i.e., timing of assessments) illustrated in Figure 1. The evaluation framework uses electronic patient-reported data collection via tablet personal computers deployed in the clinic [4]. Participants in the Pathfinders program were surveyed across multiple time-points to examine the effects of the Pathfinder intervention on patient-reported outcomes (PROs), and as reported elsewhere [5], we found that Pathfinders was helpful to patients, feasible in an academic medical center, and individuals experienced improvements in quality of life (QOL), distress and despair after 3 months of participation.

The conceptual model presumed that changes in psychosocial resources would lead to improved QOL-related outcomes. The primary purpose of this manuscript is to examine correlations between changes in the psychosocial resources that were the target of the Pathfinders intervention and benefits experienced by study participants.

## Methods

### Participants and procedures

This was a prospective, single arm, pilot study enrolling a convenience sample of eligible patients at Duke University Medical Center (2006–2008). Eligible patients were:  $\geq 18$  years of age; female; diagnosed with metastatic breast cancer; receiving chemotherapy, intravenous immunotherapy, or intravenous bisphosphonate therapy; expected to live  $\geq 6$  months; able/willing to travel to clinic at least every 4 weeks; English-literate; and consenting. Given their advanced illness and potential to die earlier than 6 months, 55 participants were enrolled to ensure that 40 individuals were available for full assessment at 6 months using the schema in Figure 1.

The Pathfinders intervention consisted of monthly visits (range, 2–4 weeks) with a trained and licensed clinical social worker over a 6-month period, which facilitated care coordination and psychosocial support. Each visit included cognitive restructuring, mind/body techniques, self-care, and end-of-life planning [5]. The main goal of the intervention was to improve the participant's QOL through the strengthening and acquisition of adaptive coping skills, recognition of inner strengths, and development of a self-care plan. Resource and outcome data were collected at baseline, 3 and 6 months using paper-based and electronic versions of validated measures. Equivalence between electronic and paper versions of the outcome surveys and patient acceptability were tested before use in the study

[4]. Electronic surveys were delivered via wireless, tablet-style, personal computers (e/ Tablets) in a clinical waiting area.

## Measures

Patients provided demographic information such as race, education, and marital status via the ePRO system. Clinical data including performance status (Karnofsky Performance Status Scale [KPS] [6]) and the Charlson Co-morbidity Index [7] were collected by study coordinators.

**Resources**—The resources targeted by the Pathfinders intervention were assessed using paper-based versions of five Likert-type scoring measures. The Brief COPE [8] is a 28-item coping inventory designed to assess a broad range of coping responses in various populations, including patients with advanced cancer. The reliability statistics for the seven subscales used in this study (active coping, humor, religion, instrumental support, self-distraction, denial and substance use) ranged from  $\alpha=0.78$ – $0.92$ . A higher score indicates increased frequency of coping style usage. The Interpersonal Support Evaluation List (ISEL) was used to measure the perceived availability of social support [9] and the total score of 40 items yielded  $\alpha=0.80$  in this study. Greater perceived availability of social support is indicated by a higher score. The Self-efficacy Scale [10] assesses one's belief that he/she can carry out a behavior necessary to reach a desired goal or achieve an expected outcome. It had good internal consistency for the total score and each of the subscales, which ranged from  $\alpha=0.81$ – $0.95$  in this study. A higher score is indicative of expectancies in achieving an outcome. Spiritual well-being was measured using the Functional Assessment of Chronic Illness Therapy - Spirituality (FACIT-Sp-12) [11], designed for use in cancer patients who may exhibit existential distress. The Meaning/Peace and Faith subscales and the total score yielded  $\alpha=0.90$ ,  $\alpha=0.93$ , and  $\alpha=0.91$ , respectively. A higher score represents better spirituality-related QOL. Finally, the 10-item Life Orientation Test-Revised (LOT-R) [12] was used to assess optimism in our sample and had good internal consistency ( $\alpha=0.82$ ). Greater optimism is indicated by a higher score.

**Outcomes**—Measures used to capture QOL-related outcomes via the ePRO system used Likert-type scoring and included the Patient Care Monitor 2<sup>TM</sup> (PCM) [13], the Functional Assessment of Cancer Therapy (FACT-G) [14], and the FACIT-Fatigue scale [15]. Two PCM subscales were used to assess psychological distress and despair. The 4-item distress ( $\alpha=0.95$ ) and 7-item despair ( $\alpha=0.93$ ) subscales yielded good internal consistency. A higher score is indicative of more symptoms. The 27-item FACT-G captured cancer-specific QOL; internal consistency for each of the subscales (physical well-being,  $\alpha=0.84$ ; social/family well-being,  $\alpha=0.79$ ; emotional well-being,  $\alpha=0.85$ ; and functional well-being,  $\alpha=0.88$ ) and total score ( $\alpha=0.91$ ) were good. A higher score is indicative of better QOL. The 13-item FACIT-Fatigue scale ( $\alpha=0.95$ ) was used to measure fatigue and had good reliability. Less fatigue is represented by a higher score.

## Statistical analysis

Participants who completed a baseline assessment and at least one follow-up assessment were included in these analyses; 50 participated in the Pathfinders intervention and 44 met criteria for these analyses. Cronbach's alpha coefficients were computed at the baseline assessment to ensure that scales were reliable and performing as expected. Only subscales with  $\alpha \geq 0.70$  were used in subsequent analyses, which included participants who completed a baseline assessment and at least one follow-up assessment.

For each subscale measurement of resource or outcome, the average rate of change from baseline was computed as the ratio of the area under the curve (AUC) for the subscale

change from baseline divided by the total time interval (baseline to last follow-up visit). The trapezoid method was used to calculate the AUC [16]. Spearman rank correlation coefficients were used to assess the relationship between the average rate of change from baseline of scales measuring resources and those measuring outcomes. Correlation coefficients were considered strong if  $r > 0.5$  and moderate if  $0.3 < r \leq 0.5$  [17].

For each resource, multiple linear regression models were used to examine the joint effect of average changes in resource-related subscales on select average outcome changes adjusted for baseline outcome scores and patient characteristics (age, education, performance status). Resource predictors included those subscales that had a univariate correlation with outcome that was significant at the 0.10 level. Given the high correlation of self-efficacy subscales, the total score was used. For the coping and spirituality resources, backwards elimination of candidate resources was used to generate a parsimonious model.

A two-sided significance level of 0.05 was used for all statistical tests. Analyses were conducted using SAS V9.1 (SAS Institute, Cary, NC).

## Results

Participants (N=44) had a mean age of 51.5 (standard deviation [SD], 11.9; range 31–79), 20% were non-Caucasian, 50% had a college degree, 75% were married, 69% were able to perform their normal activities, and 68% had no comorbidities. Mean average change (SD) in outcomes and resources from baseline were as follows: distress, -3.4 (5.0); despair, -4.4 (9.1); QOL/FACT-G, 3.5 (8.6); FACT-G Emotional, 1.7 (2.2); fatigue, 2.9 (6.3); social support, 0.1 (2.6); substance use, 0.1 (0.6); self-efficacy, 4.4 (10.9); active coping, -0.1 (1.0); spirituality, 1.5 (4.3); and optimism -0.2 (3.0).

Bivariate associations between changes in the independent variables (i.e., resources) and PROs (distress, despair, QOL, fatigue) were calculated. The following relationships were statistically significant at  $P < .05$ : coping (humor, instrumental support) and social support were moderately or strongly correlated with distress; coping (humor, religion, instrumental support), self efficacy (functioning, total score), spirituality (all subscales), and optimism were moderately or strongly correlated with despair; self-efficacy (other) was moderately correlated with physical well-being; coping (instrumental support, denial), spirituality (total score) and optimism were moderately correlated with social well-being; coping (substance use), social support, spirituality (meaning/peace, total score), and optimism were moderately or strongly correlated with emotional wellbeing; coping (self-distraction, substance use), self-efficacy (total score), and optimism were moderately or strongly correlated with functional well-being; coping (humor, instrumental support) and optimism were moderately correlated with overall well-being; and coping (humor, substance use) and self-efficacy (functioning, other, total score) were moderately or strongly correlated with fatigue.

Figure 2 presents the results of multiple linear regression models generated to inspect relationships between the average rate of change from baseline for subscales measuring resources and patient outcomes after adjustment for baseline scores and patient characteristics (age at enrollment, education, performance status). After adjustment for patient characteristics, the following resources were found to have a significant association with at least one outcome: social support with distress ( $P < .05$ ;  $R^2 = 0.89$ ); substance use with fatigue ( $P < .01$ ;  $R^2 = 0.54$ ); self-efficacy with fatigue ( $P < .01$ ;  $R^2 = 0.53$ ) and despair ( $P < .05$ ;  $R^2 = 0.90$ ); active coping with despair ( $P < .05$ ;  $R^2 = 0.90$ ); spirituality with despair ( $P < .01$ ;  $R^2 = 0.91$ ) and emotional well-being ( $P < .05$ ;  $R^2 = 0.55$ ); and optimism with emotional well-being ( $P < .01$ ;  $R^2 = 0.62$ ) and overall well-being ( $P < .01$ ;  $R^2 = 0.44$ ).

## Discussion

This pilot study examined the association between targeted psychosocial resources and QOL-related outcomes in advanced breast cancer patients, providing initial confirmation of our hypothesis that the Pathfinders participants experienced changes in social support, coping skills, self-efficacy, spirituality and learned optimism. Improvements in these targeted resources were independently associated with improvements in distress, despair, emotional well-being, overall QOL, and fatigue. The conceptual model and evaluation framework presented in Figure 1 were supported by the results in Figure 2, in which changes in psychosocial resources targeted by the intervention were associated with improved QOL-related outcomes.

While psychosocial comparative effectiveness research is in its infancy, there are a few RCTs that have examined similar associations in individuals with cancer. For example, a psycho-educational palliative care intervention (Project ENABLE), demonstrated significantly higher QOL and mood relative to those patients who did not receive the intervention [18]. Our findings of the independent association of coping with despair reinforce this approach. In addition, our finding that improved social support was independently associated with reductions in distress is consistent with RCTs of two other group support interventions, in which patients with metastatic cancer experienced significant reductions in anxiety [19,20].

Limitations of this pilot study include the lack of a control group, which prevents the ability to determine if participants had similar relationships between resources and outcomes to a similar group of patients who did not receive the intervention. However, the use of longitudinal data collection, and careful timing of assessments and related analyses assisted in the establishment of an association between resources and outcomes. Second, only women with a single cancer diagnosis (metastatic breast cancer) were enrolled, limiting generalizability. Third, the intervention was conducted predominantly by a single provider (one Pathfinder); three additional Pathfinders are in training and will deliver the intervention during the next study. Fourth, the sample size was small, this was a secondary analysis, correlations do not indicate causality, and we did not have enough participants to identify all correlations that potentially existed; however, findings were consistent with our *a priori*-developed conceptual model, which is reassuring. Finally, sub-scales within the ISEL and FACT-G overlap, which could account for observed correlations.

Despite these limitations, these pilot data provided initial confirmation that the Pathfinder participants experienced changes in targeted resources, which correlated with positive changes in outcomes. Current research supports the feasibility of the Pathfinders program and supports the conceptual model for the intervention and assessment of its impact; a more definitive experimental study design is needed to determine whether the Pathfinders intervention is superior to regular standard of care for decreasing distress and improving QOL in cancer patients.

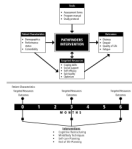
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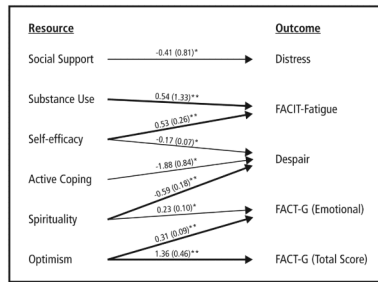
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**Figure 1.**

Pathfinders Conceptual Model and Evaluation Framework with Timeline

NOTE: Measures used in this study include: Karnofsky Performance Status and Charlson Comorbidity scales (Patient Characteristics); Brief COPE, Interpersonal Support Evaluation List, Self-efficacy Scale, Functional Assessment of Chronic Illness Therapy (FACIT)–Spirituality, and Life Orientation Test-Revised (Targeted Resources); and Patient Care Monitor, Functional Assessment of Cancer Therapy–General, and FACIT-Fatigue (Outcomes).



**Figure 2.**

Independent Associations between Resources and Quality of Life Outcomes

NOTE: All models adjusted for baseline outcome score, age, education, performance status; Numeric values represent parameter estimates (standard errors).

Abbreviations: FACT-G, Functional Assessment of Cancer Therapy – General Version; FACIT, Functional Assessment of Chronic Illness Therapy.

\* P<0.05; \*\* P<0.01