

ARTICLES

Using the COPE Intervention for Family Caregivers to Improve Symptoms of Hospice Homecare Patients: A Clinical Trial

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Purpose/Objectives: To test an intervention for hospice caregivers designed to help them better manage symptoms experienced by patients with cancer.

Design: A three-group comparative design with repeated measures.

Setting: A large nonprofit hospice that primarily provides home care.

Sample: 329 hospice homecare patients with cancer and their caregivers were randomized into three groups: a control group (n = 109) receiving standard care, a group (n = 109) receiving standard care plus friendly visits, and a group (n = 111) receiving standard care plus the COPE intervention.

Methods: Caregivers received experimental training in the COPE intervention (creativity, optimism, planning, expert information) over nine days to assist with symptom management.

Main Research Variables: Intensity of pain, dyspnea, and constipation, overall symptom distress, and quality of life (QOL). Data were collected on admission and days 16 and 30.

Findings: Although symptom intensity for three target symptoms did not decrease, symptom distress was significantly improved (p = 0.009) in the COPE intervention group. QOL was not significantly different.

Conclusions: Symptom distress, a measure that encompasses patient suffering along with intensity, was significantly decreased in the group in which caregivers were trained to better manage patient symptoms.

Implications for Nursing: The COPE intervention is effective and immediately translatable to the bedside for hospice homecare patients with advanced cancer.

Key Points . . .

- ▶ The focus of hospice care for patients with cancer is decreased distress and improved symptom intensity and overall quality of life.
- ▶ A coping intervention designed to support caregivers may have a positive effect on patients' perceived symptom distress.
- ▶ Although difficult and expensive, clinical trials with hospice populations are feasible.

patient's QOL may suffer. The hospice care team relies on primary caregivers for many aspects of symptom management (Weitzner et al., 1997). Research consistently has shown that caregivers are unable to accurately assess and report the intensity of symptoms and overall QOL of patients with cancer and patients in hospice care (Clipp & George, 1992; Masters & Shontz, 1989; McMillan, 1996b, 1996c; McMillan & Moody, 2003). Symptoms such as pain, dyspnea, and constipation commonly are seen in patients with advanced cancer, but they are assessed inadequately and managed poorly in many patients (McMillan & Tittle, 1995; Moody, Fraser, & Yarandi, 1993). Pain and dyspnea have been found to create symptom distress, significantly affecting patient QOL (McMillan, 1996a; Moody, McCormick, & Williams, 1990). If caregivers are to function as a critical part

For many patients with advanced cancer, hospices provide palliative care near the end of life and supportive care to family members with a goal of improved quality of life (QOL) for both groups (Cella, 1995). As death approaches, families may be increasingly responsible for the majority of caregiving tasks, including providing emotional support, assisting with activities of daily living, administering medication, providing nutrition, and aiding with other physical aspects of care (Laizner, Yost, Barg, & McCorkle, 1993). In addition, the family caregiver is an important communication link between the patient and hospice staff, especially as the patient becomes more debilitated (Weitzner, Moody, & McMillan, 1997).

If a caregiver is not adequately prepared to accurately report the patient's condition or provide needed care, the

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of the healthcare team, they need the skills to function effectively. Building the knowledge base and teaching an orderly problem-solving approach to care should improve symptoms for patients and result in increased QOL. The purpose of this study was to evaluate the effect of a problem-solving intervention provided to caregivers of hospice homecare patients with cancer.

Literature Review

Assessment and Management of Symptoms

Research has shown that pain, dyspnea, and constipation are among the most common symptoms experienced by patients with cancer receiving hospice care (Donnelly, Walsh, & Rybicki, 1994; Weitzner et al., 1997). Of those, pain was the most prevalent, requiring treatment in 82%–88% of patients. Although pain, dyspnea, and constipation are experienced subjectively, nurses often depend on family caregivers for information about the severity of the symptoms (Weitzner et al.). The literature suggests, however, that pain is not managed effectively and patients often are undermedicated (Brescia, Portenoy, Ryan, Krasnoff, & Gray, 1992; Gaston-Johansson, Franco, & Zimmerman, 1992; McMillan, 1996a; Paice, Mahon, & Faut-Callahan, 1991). In addition, the degree of error in family caregiver reports is high (Clipp & George, 1992; McMillan, 1996b; McMillan & Moody, 2003). The Oncology Nursing Society indicated that patients have a right to expect their pain to be relieved and that complete relief should be the goal of care (Spross, McGuire, & Schmitt, 1990).

Pain relief is a major goal of hospice care, yet a small prospective study examining pain among hospice homecare patients with cancer ($N = 25$) found that during a 24-hour period, patients continued to have pain despite their pain management regimens (McMillan & Tittle, 1995). Some patients reported average daily pain to range as high as 96.7 on a 0–100 visual analog scale. A follow-up study (McMillan, 1996a) included hospice homecare patients with cancer ($N = 118$) who were asked how much their pain was relieved (1–10). After three weeks of hospice care, pain relief was not optimal, with 42% of patients reporting relief at 5 or less, suggesting that pain management in hospice homecare patients deserves attention. Pain relief was found to be related to overall QOL ($r = 0.41$, $p < 0.001$) as well as elements of QOL, including sleeping ($r = 0.34$, $p < 0.002$) and fatigue ($r = 0.29$, $p < 0.01$).

A clinical trial was conducted with 166 patients with advanced lung cancer over six months to compare standard office care to home care provided by nonspecialized homecare nurses and home care provided by oncology homecare nurses (McCorkle et al., 1989). Results revealed that although no significant differences were found in pain intensity, the two groups receiving home care perceived significantly less symptom distress and greater independence than the office care group.

Constipation also is a common problem in hospice patients with cancer (Donnelly et al., 1994) because of the opiates needed to manage pain as well as limited food and fluid intake and lack of activity. In a group of hospice homecare patients with cancer, constipation was assessed by asking patients about symptoms of constipation (McMillan & Tittle, 1995). The study found that 84% of hospice patients had some degree of constipation, but it was recorded as a

problem in only 29% of the patients' charts. Another survey of hospice homecare patients with cancer found that 68% reported symptoms of constipation (McMillan, 2002). A chart audit at a large hospice indicated that 51% of patients with cancer were being treated for constipation (Weitzner et al., 1997). If all patients with constipation were receiving a nursing intervention, 51% would be high; however, research suggests that the number of patients suffering with constipation is even higher than 51%, and is, to some extent, probably unrecognized and untreated (McMillan, 2002; McMillan & Tittle).

Dyspnea is one of the most frequent and distressing symptoms experienced by hospice patients with advanced cancer. Research indicates that dyspnea is the fourth most common symptom in patients who present to an emergency department with advanced cancer; in addition, dyspnea is believed to be a clinical marker for cancer's terminal phase (Escalante et al., 1996). A survey of hospice patients found dyspnea to be the second most common physical symptom, with 59% requiring nursing intervention (Weitzner et al., 1997). Strategies to reduce and manage dyspnea in hospice patients have been tested only minimally. Patients, healthcare providers, and family caregivers often are frustrated and feel helpless when coping with severe, chronic dyspnea. Fewer than 20% of those suffering from chronic dyspnea obtain relief through treatment (Moody et al., 1993). In patients with chronic lung disease, Moody (1990) found that dyspnea severity directly affected functional status and QOL. The problems of dyspnea assessment and management also are of clinical importance for the QOL of hospice patients. Few intervention studies have been conducted to demonstrate methods for improving dyspnea severity or distress in patients with advanced cancer.

Little evidence is available to support a link between assessment and management (McMillan, Williams, Chatfield, & Camp, 1988), but if symptoms are better managed, patients' general condition will be improved, leading to improved QOL. In addition, although hospice programs provide significant education to caregivers, a more intensive effort with families may be needed.

Symptom Distress

Symptom distress has been defined as physical or mental upset, anguish, or suffering reported by individuals as a result of specific symptoms (Rhodes, McDaniel, & Matthews, 1998). A study of hospice homecare patients with cancer ($N = 178$) revealed that the most distressing problems experienced were lack of energy, dry mouth, pain, shortness of breath, feeling bloated, and difficulty sleeping (McMillan & Small, 2002). Furthermore, symptom distress was an important predictor of QOL in patients.

Quality of Life

Improving the QOL of patients and families is the stated purpose of hospice care. A series of studies of hospice homecare patients with cancer conducted in the 1990s revealed that patient and caregiver QOL remained stable over four weeks of hospice care (McMillan, 1996b; McMillan & Mahon, 1994). A later study showed that pain, constipation, and shortness of breath all were significantly correlated with QOL in hospice homecare patients with cancer (McMillan & Small, 2002).

Problem-Solving Training

Problem-solving training (Nezu, Nezu, & Perri, 1989) teaches patients how to use an orderly problem-solving approach when dealing with emotional and behavioral problems. Houts, Nezu, Nezu, and Bucher (1996) proposed a conceptual adaptation of the Nezu et al. problem-solving therapy approach for use with family members caring for patients with illness at home. Research using that approach has been formative in that it focused on assessing satisfaction and attitude change among participants in an education program based on the approach (Archbold et al., 1995).

Limited work has been done to develop and assess the efficacy of interventions designed to educate caregivers regarding symptom management. A quasi-experimental study evaluating a nursing intervention designed to improve the preparedness and competence of family caregivers showed that caregivers receiving the intervention were better prepared, experienced more predictable caregiving situations, and were more enriched by the caregiving process than a control group (Archbold et al., 1995); however, the effect on the care provided by caregivers to patients is unknown. In a randomized trial that included 375 older adult patients with cancer and their caregivers, the intervention group received oncology home care provided by advanced practice oncology nurses who assisted patients and taught caregivers to provide care. Older adult patients in the intervention group had significantly longer survival (McCorkle et al., 2000).

The present study sought to determine whether patients receiving standard care plus the COPE problem-solving intervention would have significantly less symptom intensity (pain, dyspnea, and constipation), less symptom distress, and better QOL compared to patients receiving standard care only or standard care plus friendly visits.

Methods

Design

The clinical trial used a three-group repeated-measures design. The study was based on the stress process model wherein patients' symptoms and symptom distress were viewed as stressors for caregivers (Pearlin, Mullan, Semple, & Skaff, 1990). Patients' perceived QOL was viewed as a mediator, and the outcome variable was caregiver QOL. Stress process models suggest that caregiver QOL can be improved through interventions that can decrease caregivers' stressors or alter caregivers' reactions to patient stressors. For example, teaching caregivers skills in managing patient symptoms, helping caregivers to appraise stressors more benignly (e.g., as a challenge rather than as an overwhelming threat), and teaching caregivers to use more problem-focused coping techniques can lead caregivers to have enhanced QOL and feelings of mastery. A meta-analysis of interventions for caregivers of patients with Alzheimer disease demonstrates that the interventions are effective in improving caregiver depression and decreasing burden (Knight, Lutzky, & Macofsky-Urban, 1993). Although little research has been conducted regarding mastery in cancer caregivers, in chronically medically ill patients, improved mastery is associated with improved functional status and QOL (Moody et al., 1990; Moody, Lowry, Yarandi, & Voss, 1997). Only patient data are reported in this article.

Sample

The sample for the present study was drawn from a large nonprofit hospice where most patients receive home care. Based on power calculations, 160 patient-caregiver dyads were sought for each group ($N = 480$ dyads). All consenting patient-caregiver dyads that met inclusion criteria were included in the study. Patients had to be adults with a diagnosis of cancer and an identified family caregiver, and both had to consent; patients and caregivers had to have at least a sixth-grade education and be able to read and understand English, have a minimum score of seven on the Short Portable Mental Status Questionnaire (SPMSQ) (Pfeiffer, 1975); and patients had to have a minimum score of 40 on the Palliative Performance Scale (PPS) (Virik & Glare, 2002). Because the study focused primarily on the management of pain, dyspnea, and constipation, patients were excluded if they did not have two of the symptoms as documented by baseline data collection.

Instruments

Pain intensity was assessed by research assistants (RAs) using a **numeric rating scale (NRS)**. Patients were asked to verbally rate their pain intensity at that moment on a scale from 0 (no pain) to 10 (worst pain) (Stewart, 1977). One advantage of an NRS is its ease of use by debilitated patients (Downie et al., 1978; Kremer, Atkinson, & Ignelzi, 1981). Previous research indicates that an NRS is valid and reliable and correlates well ($r = 0.59-0.86$) with other measures of pain intensity (Kremer et al.). A comparison among the NRS, a visual analog scale, a box scale, a behavioral rating scale, a four-point verbal rating scale, and a five-point verbal rating scale yielded similar results in the number of subjects who responded correctly, thus supporting the predictive validity of each measure. The NRS was found to be more sensitive than the other scales (Jensen, Karoly, & Braver, 1986).

A **dyspnea intensity scale** was used to assess dyspnea intensity because of its ease of administration and accuracy (Silvestri & Mahler, 1993). Patients scored dyspnea on a 0–10 scale. Reliability and validity of the one-item rating scales have been supported by a number of studies (McCord & Cronin-Stubbs, 1992; Silvestri & Mahler). Test-retest reliability ranged from 0.89–0.92, and concurrent validity with other measures ranged from 0.88–0.94 (Moody et al., 1997).

The **Constipation Assessment Scale (CAS)** is an eight-item, three-point, summated rating scale that measures the presence and intensity of constipation (McMillan & Williams, 1989). Patients rate each item as no problem, some problem, or severe problem. Scores can range from 0 (no constipation) to 16 (worst possible constipation). Validity was evaluated using the known-groups method. A significant difference ($p = 0.0001$) between the CAS scores of 32 working adults and 32 patients receiving treatment with morphine or vinca alkaloids supported the validity of the CAS. Further analysis compared the CAS scores of the patients receiving significant doses of morphine with the CAS scores of patients who had received vinca alkaloids three weeks previously. The significant difference between the two groups ($p < 0.01$) supports the sensitivity of the CAS to differentiate between moderate and severe symptoms of constipation. Test-retest with a brief delay provided strong evidence of reliability ($r = 0.98$). Alpha coefficients ($r = 0.70-0.78$) were acceptable for such a short scale.

The **Memorial Symptom Assessment Scale (MSAS)** is a self-report scale used to measure the distress caused by all symptoms (Portenoy et al., 1994). Patients first indicate the presence of a given symptom from a list provided and then score the intensity and the distress it is causing. Distress is measured on a five-point summated rating scale for 24 items, with a total distress score ranging from 0 (no distress) to 96 (very much distress). Validity was supported by high correlations with clinical status and QOL. Alpha reliabilities were 0.83–0.88 (Portenoy et al.).

The **Hospice Quality-of-Life Index (HQLI)** is a 28-item self-report tool that includes three aspects of overall QOL: psychophysiologic well-being, functional well-being, and social or spiritual well-being (McMillan & Weitzner, 1998). Total scores range from 0–280. Evidence of validity was provided by the ability of the HQLI to differentiate between hospice patients and apparently healthy controls using discriminant analysis ($p = 0.00$) and comparison of means ($p = 0.00$). HQLI scores correlated at the expected level ($r = 0.26$, $p = 0.00$) with functional status scores, providing further evidence of validity. Finally, factor analysis confirmed the factor structure of the HQLI. Reliability of the HQLI was provided by generation of coefficient alphas for total scale scores and subscale scores. Subscale alphas all were 0.84, and the total scale alpha was 0.88. Standard demographic data—age, gender, education level, and marital status—were collected from patients.

Procedures

The study was approved by the hospice's bioethics committee and a university institutional review board. The hospice also gave permission for the researchers to hire nurses and home health aides (HHAs) from its staff to work as RAs for the duration of the study. During the study, RA nurses and RA HHAs worked for the investigators rather than the hospice.

Eligible patient-caregiver dyads were identified initially by the RA data collector nurses at the beginning of each day. RA data collector nurses contacted caregivers to arrange a visit by the nurse and an RA HHA. During the visit, the study was explained, patient and caregiver consent was obtained, the patient was screened using the PPS and the SPMSQ, and baseline data were collected. The patient-caregiver dyads were randomly assigned to one of the three treatment conditions using a computerized randomization procedure accessed via telephone.

Experimental Conditions

The intervention was provided by a team that included one RA nurse and one RA HHA, and data were collected by a separate RA nurse and RA HHA team.

Group I: Caregivers in treatment group I, the control group, received standard care from the hospice staff. The hospice routinely provided some caregiver education and support about symptom management and what to expect as the disease progresses. Patients in the control group participated in the data collection process.

Group II: Caregivers in treatment group II received standard care from the hospice staff plus friendly visits made on the same schedule and lasting as long as the COPE intervention group (visit 1 = 45 minutes; visits 2–3 = 30 minutes each). However, instead of providing caregivers with training on intervention techniques, the RA nurse spent time provid-

ing individual support to caregivers, discussing their feelings, fears, and relationships with the patients. The friendly visit intervention was designed to control for the effects of researcher attention, enabling the researchers to differentiate the effect of the intervention from the effect of the extra time and attention given to the caregivers in the COPE intervention group. While the RA nurse gave the intervention, the RA HHA provided respite by remaining with the patient.

Group III: In addition to receiving standard care, the caregivers in treatment group III served as the experimental group and were taught the COPE intervention method to assist them in assessing and managing patient problems.

COPE Problem-Based Coping Intervention

The COPE intervention addresses the specific needs of families caring for patients with cancer at home (Houts et al., 1996). The model has four components. In the **creativity** component, caregiving problems are viewed from different perspectives to develop new strategies for resolving them (e.g., "I will be creative about managing my husband's pain."). In **optimism**, families should have a positive but realistic attitude toward the problem-solving process. They communicate realistic optimism to the patient by showing understanding and hope and by involving the patient as much as possible in planning (e.g., "I believe that my husband's pain can be controlled."). In the **planning** component, reasonable caregiving goals are set and the steps necessary to reach those goals are determined in advance (e.g., "On Thanksgiving, I will plan my husband's medications so he will be able to enjoy time with the family."). In **expert information**, families are taught what nonprofessionals need to know about the nature of the problem, when to get professional help, and what family caregivers can do on their own to deal with the problem (e.g., "I will look up in the *Home Care Guide [for Advanced Cancer]* how to talk to the doctor about my husband's pain."). Symptom assessment is included in the expert information element of the COPE intervention model because accurate information about symptom characteristics and intensity is essential to know when to call for professional help as well as for planning what caregivers can do. Assessment techniques for pain, constipation, and dyspnea were emphasized in the expert information given to family caregivers. Caregivers were given three symptom assessment tools: a constipation assessment scale and NRSs for pain and dyspnea. They were taught the need for careful assessment and how to apply the tools. As part of their plans for managing symptoms, caregivers were encouraged to assess pain and dyspnea at least twice daily and constipation once daily on a routine basis and to record findings in a patient symptom diary. The ratings were the foundation for the actions they took in calling hospice staff and managing the symptoms at home. Research on problem-solving training and therapy indicates that applying the four problem-solving principles should lead to better problem solving and reduced stress for caregivers dealing with the problems (Nezu et al., 1989).

The COPE program for families teaches and supports caregiver problem solving in three ways. First, written information is organized to facilitate problem solving in the *Home Care Guide for Advanced Cancer* (Houts, 1997). Twenty-three patient problems are included in the guide for easy reference by caregivers. The current problem-solving intervention emphasized management of pain, dyspnea, and constipation to maximize control of the symptoms and serve

as a model for the development of plans for other symptoms and problems. The caregivers in the intervention group received three visits during the nine-day intervention from an experienced RA nurse who had been trained in the COPE intervention problem-solving principles, in use of the *Home Care Guide for Advanced Cancer* (Houts), and in use of the three symptom assessment tools. Caregivers received copies of the *Home Care Guide for Advanced Cancer* for personal use. Second, the RA nurse demonstrated the use of COPE intervention problem-solving principles in caring for a patient with cancer. An important part of the intervention was continuing support for problem solving by project staff over the course of three home visits. The RA nurse asked about plans, encouraged developing plans, and helped as necessary in the development of new plans. As much as possible, the RA nurses helped caregivers to develop plans rather than creating plans for them. Third, the RA nurses called caregivers between each of the intervention visits. During the calls, the intervention nurses asked about current problems regarding the targeted symptoms, offered support in solving the problems, and answered questions as needed. In addition, caregivers were given a pager number for the RA nurse and encouraged to call if other questions arose.

Staff Training

A four-day training session was conducted for the RA nurses and RA HHAs and included how to provide the COPE intervention training session regarding managing patient problems and how to use the *Home Care Guide for Advanced Cancer* (Houts, 1997). In addition, the RA intervention nurses were taught how to conduct a friendly visit without contaminating the study by doing or teaching problem solving. The RA nurses role played several scenarios for practice. Training also was provided for the RA data collector nurse and the RA data collector HHA regarding how to identify and screen subjects, how to explain the study to obtain consent, and how and when to collect the data, ensuring complete data on each questionnaire.

Integrity of the Intervention and Manipulation Checks

To ensure consistent compliance by the RA nurses with the protocols, all intervention visits were tape recorded. The investigators reviewed 10% of the tapes each month to determine whether all of the interveners were providing the interventions according to the protocol and to ensure that the protocols were not being mixed between the friendly visits and COPE intervention groups.

Possible interference by hospice staff members was minimized. They were told that if a patient or caregiver asked a question about the study, the individual should be referred to the RA intervention nurse whose pager number was displayed prominently on all study materials.

Hospice staff could have changed their behavior toward caregivers because of their knowledge of the study. To monitor drift in the standard care provided, during the final data collection period, the researchers asked the caregivers to estimate how much time they believed the hospice nurse spent talking about the three target symptoms. Because the number remained constant throughout the study, the researchers have evidence that the hospice staff nurses did not change their behavior as a result of the project.

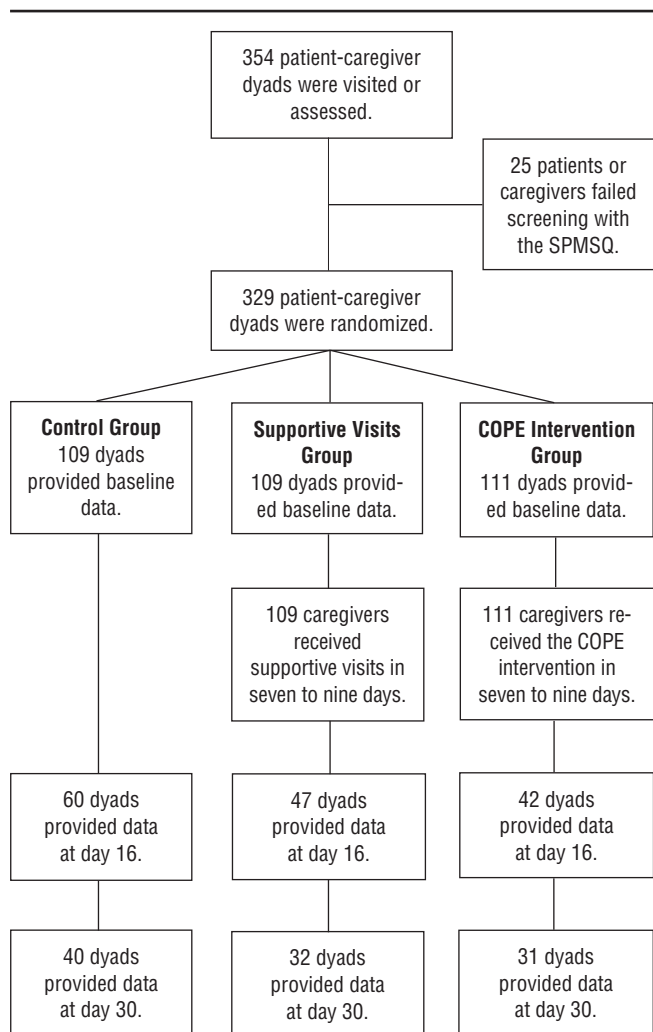
Data Collection

Baseline: Within 24–48 hours after hospice admission, the RA HHA interviewed the patients independently (away from the caregivers) to obtain demographic information and administered the HQLI, pain intensity scale, dyspnea intensity scale, and CAS. The RA nurse simultaneously interviewed the caregivers. The three symptom assessments determined which problems the patient was experiencing so the intervention for group III could be tailored to each patient’s situation. In addition, patients completed the MSAS to assess for distress caused by symptoms other than pain, dyspnea, or constipation.

Postintervention: Two weeks after entry into the study (day 16 of hospice admission) and two weeks later (day 30), patients again were asked to report symptom intensity and complete the MSAS and HQLI.

Data Integrity

A coinvestigator ensured that all patients admitted to the study met all study criteria by performing a random survey of 10% of all cases each month. To ensure that questionnaires were answered completely, data collectors were instructed to



SPMSQ—Short Portable Mental Status Questionnaire

Figure 1. Progression of Patients Through the Study

review each form as the patient completed it and gently point out any omissions. Previous experience with hospice patients indicates that gentle reminders are critical in avoiding missing data. Finally, the RA HHA and RA data collector nurses exchanged forms before leaving the home and checked one another's forms to ensure that no data were omitted.

Data Analysis

Prior to examining longitudinal changes in the outcome measures by intervention group, a multivariate analysis of variance was performed to test for differences between groups to verify that the randomization scheme resulted in groups that were equivalent at baseline in terms of patients' age, gender, functional status, and education. To examine longitudinal changes in the outcomes across the three measurement times (baseline, day 16, day 30), the researchers employed random-effects regression models to the data (Gueorguieva & Krystal, 2004; Singer & Willett, 2003). Several advantages exist to using that method of data analysis in terms of the estimation of longitudinal changes in functioning; chief among the advantages is the ability to include individuals for whom complete data are not available, which is directly relevant to the current case, given the large and expected amount of attrition across the 30-day follow-up period (see Figure 1). Thus, the analyses that are reported include patients who contributed any data for the three measurement points.

For each of the dependent variables, four effects were estimated corresponding to an initial intercept, a group effect that examines whether differences at the intercept varied as a function of intervention group or longitudinal changes over time (time), and a group by time interaction to examine whether longitudinal changes varied as a function of intervention group. In cases where the group by time interaction was statistically significant, separate random-effects models estimating longitudinal changes over time were computed for each of the intervention groups to decompose the effects.

Results

The baseline demographic characteristics for the sample are shown in Table 1, presented by intervention group. A comparison of the characteristics revealed no statistically significant differences among the groups, indicating that the randomization procedure produced groups that were comparable. On

average, the hospice patients were aged approximately 70 and mostly male and had a high school education, PPS scores of 50, and SPMSQ scores of less than 9 points.

The results of the random-effects models for the patient outcomes are displayed in Table 2, with the critical outcome being the time by intervention group interaction term. If statistically significant, it indicates that the intervention groups experienced different trajectories of change over the follow-up period. The other terms in Table 2 indicate scores at the first measurement point (intercept), whether the intervention groups differed in terms of their scores at baseline (intervention group), and whether statistically significant changes were present for all patients (time). Only one measure, the MSAS (symptom distress), exhibited a statistically significant intervention group by time interaction. By contrast, none of the other variables exhibited a significant time by intervention group interaction, nor were the main effects of time and intervention group statistically significant.

To better understand the significant time by intervention group interaction for the MSAS, the researchers computed separate random-effects models on MSAS scores comparing the standard care with the standard care plus support group, as well as a model comparing standard care with the COPE intervention. Again, the presence of a significant time by intervention group interaction provided evidence for different trajectories of change among the three groups. The results indicate that the interaction term for the supportive visits comparison was not statistically significant (estimate = -0.035, standard error = 0.073, $p = 0.633$), but the effect was statistically significant when comparing against the COPE intervention (estimate = -0.101, standard error = 0.039, $p = 0.013$). Figure 2 shows the raw MSAS scores for the three intervention groups across the follow-up period. Group III exhibited the greatest declines over the follow-up period, accounting for the significant interactions that were observed.

Discussion

The COPE intervention, although directed at primary caregivers, had a positive effect on the overall symptom distress of patients with cancer in hospice care, which supports the earlier work of McCorkle et al. (1989) who reported no improvement in pain intensity in patients with cancer receiving home care but a significant improvement

Table 1. Baseline Demographic Characteristics by Intervention Group

| Characteristic | Standard Care (N = 109) | | Standard Care and Support (N = 108) | | Standard Care and COPE Intervention (N = 111) | | p |
|--|----------------------------|-------|--|-------|--|-------|-------|
| | n | % | n | % | n | % | |
| Female gender | 48 | 44 | 42 | 39 | 41 | 37 | 0.841 |
| Characteristic | \bar{X} | SD | \bar{X} | SD | \bar{X} | SD | p |
| Age (years) | 70.12 | 12.58 | 71.02 | 12.12 | 70.84 | 10.99 | 0.530 |
| Education (years) | 12.49 | 2.80 | 12.28 | 3.21 | 11.84 | 3.41 | 0.313 |
| Palliative Performance Scale score | 51.42 | 9.96 | 52.57 | 11.09 | 54.50 | 7.88 | 0.064 |
| Short Portable Mental Status Questionnaire score | 8.85 | 1.40 | 8.91 | 1.37 | 8.58 | 1.69 | 0.228 |

Table 2. Summary of Random-Effects Models Over the Follow-Up Period, as a Function of Intervention Group Status

| Outcome and Model Term | Estimate ^a | SE | p |
|-------------------------|-----------------------|-------|---------|
| Symptom distress | | | |
| Intercept | 21.243 | 1.899 | < 0.001 |
| Time | 0.144 | 0.081 | 0.079 |
| Intervention group | 0.409 | 0.875 | 0.641 |
| Group by time | -0.101 | 0.038 | 0.009 |
| Breathlessness | | | |
| Intercept | 2.807 | 0.426 | < 0.001 |
| Time | 0.017 | 0.023 | 0.459 |
| Intervention group | 0.148 | 0.197 | 0.453 |
| Group by time | -0.003 | 0.011 | 0.771 |
| Pain | | | |
| Intercept | 2.912 | 0.405 | < 0.001 |
| Time | 0.028 | 0.023 | 0.215 |
| Intervention group | -0.039 | 0.187 | 0.836 |
| Group by time | -0.012 | 0.011 | 0.268 |
| Constipation | | | |
| Intercept | 3.348 | 0.454 | < 0.001 |
| Time | -0.015 | 0.025 | 0.551 |
| Intervention group | -0.170 | 0.208 | 0.416 |
| Group by time | -0.001 | 0.012 | 0.973 |
| Quality of life | | | |
| Intercept | 210.054 | 5.556 | < 0.001 |
| Time | 0.031 | 0.240 | 0.899 |
| Intervention group | -2.994 | 2.562 | 0.246 |
| Group by time | 0.132 | 0.113 | 0.246 |

^a Unstandardized estimates from the random-effects models are shown.
SE—standard error

in perceived symptom distress. The rationale for patients in both studies perceiving significantly less distress from symptoms in the face of pain that shows no significant improvement is unclear. Distress in the present study was described to patients as how much the symptoms distressed or bothered them and was believed by the investigators to include an element of suffering. Perhaps greater discussion about symptoms with patients and caregivers relieved some of the distress of both members of the dyad, even though the actual intensity did not decrease. On a practical level, the study's results indicate that patients are better able to tolerate symptoms such as pain, constipation, and dyspnea although the intervention was not successful in eliminating them. The results from the caregiver data (McMillan et al., 2006) showed that caregivers perceived less distress from symptoms and less burden from caregiving as a result of the COPE intervention. Clearly, the intervention that helped primary family caregivers to perceive less distress from patient symptoms had a similar, albeit indirect, effect on patients. Many patients with advanced cancer do not receive hospice care; therefore, the intervention may be helpful to them and their caregivers. Further study is warranted.

A limitation of the study is that the protocol as funded did not involve auditing the behaviors of caregivers to determine whether their symptom management changed and whether any changes that were made were appropriate and effective. Future studies should include such important data.

Patients felt less distress or bother, which is encouraging, but their pain, constipation, and dyspnea intensity did not

show concomitant improvement. Perhaps that was because over the 30 days of data collection, patients' cancers and cancer-related symptoms naturally would have worsened as death neared. Thus, maintaining stability in patients' symptom intensity actually may be an improvement over what they might have experienced in the natural course of events. In addition, the focus of hospice care is on patient symptom management; therefore, the symptoms might have improved or remained stable equally over groups because of the effectiveness of standard hospice care.

No concomitant improvement in QOL scores was seen, which was unexpected. Previous research showed total symptom distress scores from the MSAS to be a significant predictor of overall QOL ($p < 0.001$) (McMillan & Small, 2002). Further research is needed.

Although not effective in improving all outcomes, the COPE intervention was effective in decreasing overall symptom distress in the study's patients. Because the COPE intervention has been manualized (i.e., a manual is available from the authors), it is easily replicable and can be used by professionals providing end-of-life care in a variety of contexts. The findings may stimulate further research on the intervention and others like it and contribute to the development of greater evidence-based practice for patients with cancer who are near the end of life.

As might be expected in studies conducted with hospice populations, accrual was slow and attrition was high. Because the sample was smaller than anticipated, model testing could not be conducted. Nationally, 37% of patients die within seven days of admission to hospice and the median length of stay was approximately 22 days during the years of the study (National Hospice and Palliative Care Organization, 2005). Patients who were admitted to the hospice often were too ill to participate in the study, and despite careful screening, those who did participate were likely to die before all data were collected. A detailed discussion of the accrual and attrition problems encountered in the present study are available in McMillan and Weitzner (2003).

The similarity of the groups at baseline supports the success of the telephone randomization procedure that was used in

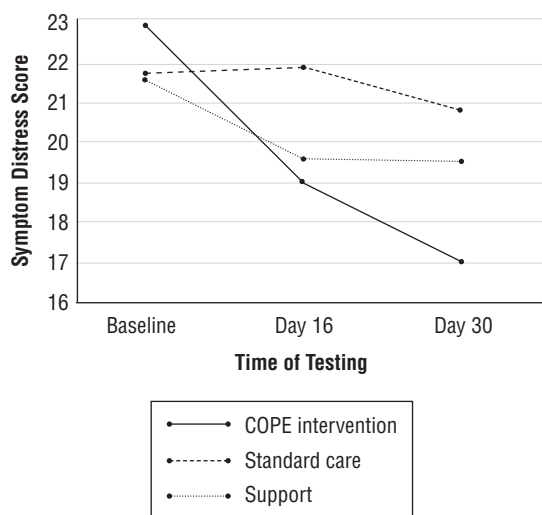


Figure 2. Memorial Symptom Assessment Scale Scores Across the Follow-Up Period by Intervention Group

the study. Demographic data mirror national results in some important ways. The average older age of the study patients is consistent with the national average. According to the National Hospice and Palliative Care Organization (2005), most hospice patients (63%) are aged 75 or older. In addition, the study's patients all were receiving home care compared to 96% of patients nationally. Although most hospice patients nationally are female, the current study's patients were predominantly male, which might be related to the requirement of a family caregiver. Some female patients may have outlived spouses and thus were not eligible for the study because they had no available caregiver. Previous studies of hospice patients that included patient-caregiver dyads consistently have shown that patients are more likely to be male whereas caregivers are more likely to be female (McMillan, 1996a, 1996c; McMillan & Mahon, 1994).

The researchers were encouraged that patient symptom distress was improved indirectly by providing an intervention to caregivers with a maximum of three training sessions. Combined with the caregiver outcomes, such findings provide strong support for the viability of the COPE intervention. Many patients with cancer face the end of life without the benefit of hospice services, and the intervention might be even more effective for them. Further research is needed.

Conclusions

Although all outcome variables did not show improvement, the improvement in symptom distress was significant and results are important. Results of this study support earlier work and provide further evidence of the importance of supporting caregivers as they provide care for hospice patients with cancer. Although research with hospice patients is difficult, the study demonstrated the viability of conducting clinical trials with patients near the end of life and provided evidence of the efficacy of the COPE intervention. The intervention is manualized and ready for translation to bedside care, but further research is needed with cancer and noncancer populations and with patients in hospice and nonhospice settings.

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