ORIGINAL INVESTIGATION

The Comprehensive Care Team

A Controlled Trial of Outpatient Palliative Medicine Consultation

Michael W. Rabow, MD; Suzanne L. Dibble, DNSc, RN; Steven Z. Pantilat, MD; Stephen J. McPhee, MD

Background: Little is known about the use of palliative care for outpatients who continue to pursue treatment of their underlying disease or whether outpatient palliative medicine consultation teams improve clinical outcomes.

Methods: We conducted a year-long controlled trial involving 50 intervention patients and 40 control patients in a general medicine outpatient clinic. Primary care physicians referred patients with advanced congestive heart failure, chronic obstructive pulmonary disease, or cancer who had a prognosis ranging from 1 to 5 years. In the intervention group, the primary care physicians received multiple palliative care team consultations, and patients received advance care planning, psychosocial support, and family caregiver training. Clinical and health care utilization outcomes were assessed at 6 and 12 months.

Results: Groups were similar at baseline. Similar numbers of patients died during the study year ($P=.63$). After the intervention, intervention group patients had less dyspnea ($P=.01$) and anxiety ($P=.05$) and improved sleep quality ($P=.05$) and spiritual well-being ($P=.007$), but no change in pain ($P=.41$), depression ($P=.28$), quality of life ($P=.43$), or satisfaction with care ($P=.26$). Few patients received recommended analgesic or antidepressant medications. Intervention patients had decreased primary care ($P=.03$) and urgent care visits ($P=.04$) without an increase in emergency department visits, specialty clinic visits, hospitalizations, or number of days in the hospital. There were no differences in charges ($P=.80$).

Conclusions: Consultation by a palliative medicine team led to improved patient outcomes in dyspnea, anxiety, and spiritual well-being, but failed to improve pain or depression. Palliative care for seriously ill outpatients can be effective, but barriers to implementation must be explored.

Arch Intern Med. 2004;164:83-91

My body betrayed me. I wasn't ready to be old.
A 62-year-old woman with end-stage congestive heart failure

DEFICIENCIES IN MEDICAL care for patients at the end of life are well documented, prompting initiatives to improve palliative medicine for diverse patient populations across a wide variety of settings.[1-4] Quality end-of-life care requires attention to the domains of physical, psychological, social, and spiritual well-being; advance care planning; and preparation for death.[5-7] Although hospice provides comprehensive end-of-life care, only one quarter of dying Americans use it.[8] Hospice follows a transition model of palliation, in which curative attempts are abandoned in favor of comfort care, largely by patients with diseases that have a relatively predictable clinical course, such as metastatic cancer.

Most Americans, however, die of chronic illnesses without predictable prognoses, such as chronic obstructive pulmonary disease (COPD) and congestive heart failure (CHF),[9,10] often after suffering with significant symptoms.[11,12] The transition model of hospice care does not serve these patients well, as most do not want to choose between curative treatment and symptom relief.[5,11,13-15] A broader model of palliative medicine would offer aggressive symptom management and comprehensive care to the large percentage of outpatients with advanced illness who are still pursuing aggressive management or cure of their disease.[16,17] Such outpatient palliative medicine has received little rigorous evaluation but may become increasingly relevant as the number of elderly people living with serious chronic illness increases.[18-23]

We conducted a controlled trial of an intervention in which an interdisciplinary team offered palliative medicine con-

From the Department of Medicine (Drs Rabow, Pantilat, and McPhee) and the Institute for Health and Aging (Dr Dibble), University of California, San Francisco.
The authors have no relevant financial interest in this article.

©2004 American Medical Association. All rights reserved.

Downloaded From: http://archinte.jamanetwork.com/ on 05/14/2015

sultation and direct services to outpatients, their families, and their primary care physicians (PCPs), in addition to usual primary care. In general, these patients were engaged in aggressive attempts to cure or manage disease and not necessarily considered to be at the end of life.

METHODS

We compared physical, psychological, social, and spiritual outcomes between an intervention group of patients receiving a multifaceted, outpatient, palliative medicine consultation intervention plus usual primary care and a control group receiving only usual primary care.[24]

SETTING

The study was performed within the 70-physician general medicine practice of a tertiary care, university medical center located in a large urban setting and serving an ethnically diverse population. Patients are cared for by academic faculty and house staff, and generally are insured via Medicare or managed care organizations, with a minority of Medicaid or self-pay patients. For administrative purposes, patients and physicians of the general medical practice are divided into 2 equivalent modules (GMA and GMB) housed in the same building, but with separate waiting areas and nursing and clerical staff.

On the basis of a coin flip, patients in one clinic module (GMA) were assigned to be the intervention group and patients in the second module (GMB) were assigned to the control group. Although individual patients were not randomized to the intervention, each patient's initial assignment to the practice modules was based only on appointment and space availability at the time of enrollment, with no other differences in composition. Similarly, physicians are initially assigned to 1 of the 2 practice modules solely on the basis of space availability in the practice at the time of hiring. Physicians and patients assigned to one module did not cross over to the other; physicians in the control module did not care for any patients in the intervention group and thus received no education or support from the intervention team.

SUBJECTS

We invited physicians in both practice modules to refer adult patients with diagnoses of cancer, advanced COPD, or advanced CHF, whom they believed had a life expectancy of 1 to 5 years and who were not yet ready for hospice care. To assist PCP recall of potentially eligible patients, we provided physicians with lists of all patients they had seen in the previous 3 months, as well as patients identified by computerized medical record or billing data as having one of the relevant diagnoses. We invited all eligible patients referred by their PCP to participate. We excluded patients with nonmelanoma skin cancers, dementia, or psychosis; those enrolled in hospice care; and those unable to complete a written survey in English or Spanish. The PCPs and patients were informed that GMA was assigned to the intervention arm and GMB to the control arm. Because they received no direct benefit from the study, control patients received participation incentives with grocery store gift certificates.

THE COMPREHENSIVE CARE TEAM INTERVENTION

We provided all intervention patients with a newly developed 1-year program delivered by an interdisciplinary palliative medicine team called the Comprehensive Care Team (CCT).[24] The CCT was composed of a social worker, nurse, chaplain, pharmacist, psychologist, art therapist, volunteer coordinator, and 3 physicians who addressed physical, emotional, and spiritual issues. All team members, except the volunteer coordinator, had expertise in palliative care. The program integrated PCP consultation, case management, volunteer and group support, chaplaincy consultation, and artistic expression.[25-34]

The CCT intervention included 7 main components. First, consultation with PCPs was based on in-depth and follow-up patient assessments conducted by the social worker. Assessments were presented to the entire CCT at regularly scheduled team meetings directed by one of the CCT physicians. The PCPs did not attend these CCT meetings but often had informal discussions with the CCT social worker and physicians. At 3 points (study entry, midway, and study completion), the CCT developed recommendations that were offered to the patient's PCP via a written letter and e-mail. Recommendations were offered in the following 5 domains: physical symptoms, psychological well-being, social support, spiritual well-being, and advance care planning. The CCT physicians based their suggestions on information from validated patient surveys and the social worker assessment, but rarely directly interviewed or examined the patient.

Second, the social worker provided case management and offered psychological support in person and by telephone. The social worker also encouraged patients to address issues of advance care planning, including surrogate decision makers, prognosis, funeral arrangements, and wills.

Third, a nurse provided family caregiver training and support through formal classes and informal individual consultation.

Fourth, a pharmacist performed a medical chart review of patient medications, looking in particular for drug-drug interactions and unnecessarily complex medication regimens.

Fifth, a chaplain offered each patient spiritual and psychological support.

Sixth, patients and their families were invited to monthly support groups that included discussions about symptom management and advance care planning, as well as art projects called "art experientials" (available at: http://dgim.ucsf.edu/cct/what_art_exp.htm) designed to explore emotions relating to illness and relationships.

Seventh, medical and pharmacy students provided volunteer patient support and advocacy through weekly telephone contacts with patients, monthly visits, and regular communication with the CCT about patient needs.[35]

DATA COLLECTION METHODS

After obtaining study approval from the University of California, San Francisco Committee on Human Research and written informed consent from participating patients, we collected data from written patient surveys, retrospective review of the medical center's computerized medical and billing records, and exit interviews with intervention patients.

Questionnaire Data

At study enrollment (time 1), 6 months (time 2), and 12 months (time 3), we collected data via a written questionnaire on functional status and multiple study outcomes (dyspnea, pain, sleep, anxiety, depression, spiritual well-being, quality of life, health care satisfaction, and advance care planning). A member of the CCT clinical team (for intervention patients) or research staff (for controls) brought the survey to the study subject at home or during a clinic visit and supervised its completion. The survey was a compilation of previously validated instruments, as detailed below.

Physical Functioning and Symptoms. The Rapid Disability Rating Scale-2[36] provided a measure of patient functional status, with 18 items using a 4-point Likert scale. Scores can range from

©2004 American Medical Association. All rights reserved.

Downloaded From: http://archinte.jamanetwork.com/ on 05/14/2015

18 (no disability) to 72 (maximal disability). Dyspnea was measured using the University of California, San Diego Shortness of Breath Questionnaire.[37] This instrument, consisting of 2 subscales scored on a 5-point Likert scale, was developed for patients with moderate-to-severe lung disease, and assesses dyspnea during an average day during the past week. The first 21-item subscale measures the degree to which dyspnea interferes with various daily activities. The second 3-item subscale assesses the degree to which dyspnea limits daily life. Pain was assessed using the Brief Pain Inventory,[38] which evaluates worst, least, average, and current pain during the last 24 hours, using a scale of 0 to 10. We also asked respondents to list current pain medications and treatments. Sleep quantity and quality were assessed using 6 sleep items from the Medical Outcomes Study.[39] Sleep was assessed during the preceding 4 weeks and was scored on a 6-point Likert scale, with a higher score indicating better sleep.

Psychosocial and Spiritual Well-being. Anxiety was assessed using the 6-item anxiety scale from the well-validated, 5-point Likert scale Profile of Mood States.[40] Depressive symptoms were evaluated using the 20-item Center for Epidemiological Studies Depression Scale.[41] Higher overall scores indicate greater depressive symptoms, with a cutoff score of 16 or greater identifying cases of depression. Spiritual well-being was evaluated using the 20-item Spiritual Well-Being Scale,[42] which includes an existential and a religious subscale. Quality of life was assessed using the Multidimensional Quality of Life Scale–Cancer Version,[43] a 17-item, sex-specific instrument with an 11-point Likert scale. Health care satisfaction was assessed with 25 relevant items from the Group Health Association of America Consumer Satisfaction Survey.[44] This instrument uses a 5-point Likert scale, with higher scores indicating greater satisfaction.

Advance Care Planning. The questionnaire also asked patients whether they had completed or considered a durable power of attorney for health care, funeral plans, and plans for disposition of possessions after death. Patients responded with yes or no answers.

We pretested the questionnaire with patients meeting inclusion criteria in a different general medicine practice. The questionnaire was then translated into Spanish and back-translated to ensure lexical equivalency by a professional bilingual medical researcher. High standardized α coefficients (range, 0.75-0.98) provided evidence of good reliability of the individual survey instruments in this study population. Patients could elect to complete the questionnaire in English or Spanish only; 1 patient chose the Spanish instrument. The questionnaire required approximately 1 hour to complete.

Medical Record Data

The medical center's computerized medical record identifies all office visits, emergency department visits, and hospitalizations. This electronic record lists medical problems and medications prescribed, as entered in the written medical record by treating physicians. At study completion, a trained research assistant, masked to patients' intervention versus control group assignment, reviewed the computerized medical records of all study subjects during the study period. Visits to the general medicine clinic, specialty clinics, urgent care clinic, and emergency department were tabulated. In addition, the numbers of hospitalizations and days hospitalized were calculated. Finally, we recorded the analgesic and antidepressant medications documented on the computerized medication list at study entry or added during the study period.

Although analysis of cost data is preferable, we were able only to acquire data on charges using the medical center's computerized billing system. At study completion, a trained research assistant reviewed the computerized billing record and identified all charges for office visits, emergency department visits, and hospital stays for all study participants during the study period. Medication, out-of-pocket, and outside hospitalization charges were not obtained.

Exit Interview Data

Intervention patients completing the 1-year intervention participated in a semistructured exit interview with the CCT social worker. Patients were asked about the timing of their introduction to the CCT, their level of satisfaction with the various elements of the CCT intervention, and the effect of the CCT on their relationships with their family, their PCP, and the medical center. Patients were asked to provide yes or no responses and then, if they wished, to answer in greater detail. Finally, we obtained information about the location and setting of a patient's death from their PCP.

ANALYTIC METHODS

We analyzed data from patients who completed all 3 surveys. All data were double entered and analyzed using the CRUNCH statistical program.[45]

We addressed 2 questions for each clinical outcome using the analysis of covariance statistic. We first determined whether there were significant group differences in mean outcome scores over time. Then, to account for the possibility that similar group means might be found only because outcomes improved over time for one group while worsening for the other, we conducted analyses of group × time interactions. To control for baseline group differences, we controlled for the time 1 values by entering them as covariates in the analysis of covariance equation. The adjusted means presented herein account for the influence of the time 1 values. All medical center charges for each patient during the study period were summed, and intervention and control group means were calculated. For advance care planning, utilization, and charge data, we used the *t* test statistic to compare group means. A cutoff of $P \leq .05$ determined statistical significance. From the exit interviews, we tabulated the discrete responses.

SAMPLE-SIZE AND POWER CALCULATIONS

A power calculation based on baseline pain scores among all study participants indicated a greater than 90% power ($\alpha = .05$) to detect a 10% change in average pain score on a 0- to 10-point scale for a sample size of 50 in each group.

RESULTS

The GMA and GMB physicians referred a similar number of patients (164 and 166, respectively), and a similar number of these patients met eligibility criteria (118 in the GMA and 113 in the GMB). Fifty intervention patients and 40 control patients were enrolled. Among eligible patients, 57.6% of referred intervention patients and 64.6% of referred control patients refused to enroll in the study. Being too ill was the most frequently given explanation for refusal to participate by patients in both groups.

The mean age of study participants (N = 90) was 68.6 years. Most were women (64%), white (53%), US citizens (69%), living with someone (57%), unmarried (73%), and retired (62%). Mean education level was 13.5 years (**Table 1**). Patients in the control (n = 40) and interven-

©2004 American Medical Association. All rights reserved.

Downloaded From: http://archinte.jamanetwork.com/ on 05/14/2015

Table 1. Demographic Characteristics of Patients in the Control and Intervention Groups*

Characteristic	Patient Groups: Control (n = 40)	Patient Groups: Intervention (n = 50)	Statistic†	*P* Value
Age, mean (SD), y	69.4 (11.2)	67.9 (13.9)	$t = 0.57$	.57
Education, mean (SD), y	13.8 (2.9)	13.3 (4.0)	$t = 0.61$	.54
BMI, mean (SD)	26.6 (6.1)	25.2 (7.8)	$t = 0.93$	.35
Functional status, mean (SD)‡	25.1 (7.8)	27.5 (6.2)	$t = 1.61$	.11
Sex				
Female	21 (52)	37 (74)	3.59	.05
Male	19 (47)	13 (26)		
Primary diagnosis				
Cancer	17 (42)	13 (26)	3.93	.14
CHF	14 (35)	17 (34)		
COPD	9 (22)	20 (40)		
Ethnicity				
White	26 (65)	22 (44)	3.14	.06
Other	14 (35)	28 (56)		
US citizen				
Yes	29 (72)	33 (66)	0.09	.65
No	11 (27)	16 (32)		
Live alone				
Yes	18 (45)	21 (42)	0.01	.83
No	22 (55)	29 (58)		
Marital status				
Married	12 (30)	12 (24)	0.16	.63
Other	28 (70)	38 (76)		
Employment				
Retired	27 (67)	29 (59)	0.35	.51
Other	13 (32)	21 (42)		
Status at study end				
Died during study	5 (12)	10 (20)	0.92	.63
Lost to follow-up	4 (10)	5 (10)		
Completed study	31 (77)	35 (70)		

Abbreviations: BMI (calculated as weight in kilograms divided by the square of height in meters); CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease.
*Unless otherwise indicated, data are number (percentage) of patients. Percentages have been rounded and may not total 100.
†Unless otherwise indicated, statistics are calculated as χ^2.
‡Measurement is described in the "Data Collection Methods" subsection on the "Methods" section.

tion (n=50) groups were similar with regard to all of these sociodemographic characteristics, except that there were more women in the intervention group ($P=.05$). There was no significant group difference ($P=.15$) in baseline mean functional status on the Rapid Disability Rating Scale (27.5 [SD, 6.2] for the intervention group; 25.1 [SD, 7.8] for the control group). Mean baseline forced expiratory volume in 1 second for patients with COPD was 1.29 (SD, 0.32), and the mean baseline ejection fraction for those with CHF was 46.9% (SD, 13.0), with no significant difference between groups ($P=.85$ and $P=.40$, respectively).

Fifteen intervention patients (30%) and 9 controls (23%) did not complete the intervention, including 10 intervention patients (20%) and 5 controls (13%) who died (Table 1). There were no significant group differences between the number of patients who died ($P=.63$) or who failed to complete the study for any other reason (loss of cognitive capacity, loss to follow-up, or refusal to participate). Only a single intervention patient refused to continue to participate, owing to a move outside the region. Patients who died and those who did not complete the study for other reasons did not differ significantly from patients who completed the study with regard to age ($P=.80$ and $P=.34$, respectively), sex ($P>.99$ and $P=.71$, respectively), or underlying disease ($P=.17$ and $P=.59$, respectively).

Table 2. Baseline Outcome Measures in the Control and Intervention Groups*

Outcome Measure	Patient Groups: Control (n = 40)	Patient Groups: Intervention (n = 50)	*P* Value for Group Difference
Physical			
No. (%) with "any" dyspnea	34 (85)	42 (84)	.90
Dyspnea interferes score	36.1	44.8	.46
Dyspnea limits score	36.1	44.5	.38
No. (%) with "any" pain	31 (77)	45 (90)	.18
Average pain score	4.1	4.1	.71
Sleep quantity	6.1	6.4	.98
Sleep quality	11.2	11.0	.88
Psychological			
No. (%) with "any" anxiety	34 (85)	40 (80)	.54
Anxiety score	6.1	7.4	.21
Depression score	16.8	19.1	.26
No. (%) with CES-D ≥16	25 (74)	19 (48)	.83
Spiritualtiy score	95.6	94.3	.18
Total quality of life score	67.7	63.2	.25
Single-item quality of life score	7.4	6.9	.95
Satisfaction with care score	73.7	77.0	.69
Attitude toward care score	13.4	14.0	.27
Advance care planning, No. (%) of patients			
DPOA-HC paperwork	16 (40)	19 (38)	.91
Plans for possessions	24 (60)	20 (40)	.13
Funeral plans	14 (35)	14 (29)	.66

Abbreviations: CES-D indicates Center for Epidemiological Studies Depression Scale; DPOA-HC, durable power of attorney for health care.
*Unless otherwise indicated, data are mean scores.

BASELINE OUTCOME MEASURES

There were no significant baseline group differences in physical symptoms, psychological well-being, spiritual well-being, satisfaction, or advance care planning measures (**Table 2**).

USE OF CCT SERVICES

Among intervention patients who completed the study, 24 patients (69%) would have liked to receive CCT services earlier in the course of their illness. No patient reported a wish to defer receiving CCT services until later in their illness.

In addition to the 3 formal assessments, the social worker provided each intervention patient an average of 3.8 in-person and 13.0 telephone contacts during the year. The social worker contacted each patient's PCP an average of 1.6 times and contacted each patient's family caregivers an average of 2.8 times. As a result of CCT case management, 37 patients (74%) received new durable medical equipment or social services to which they were entitled through existing public or commercial pro-

©2004 American Medical Association. All rights reserved.

Downloaded From: http://archinte.jamanetwork.com/ on 05/14/2015

Table 3. Physical Symptoms of Patients in the Control and Intervention Groups Over Time

Symptoms (Possible Score)	Patient Groups* Control (n = 40) Time 2	Control (n = 40) Time 3	Intervention (n = 50) Time 2	Intervention (n = 50) Time 3	Statistic ANCOVA F (*P* Value) Between Groups	Group × Time Interaction
Dyspnea†						
Degree dyspnea interferes (0-105)	40.3	40.6	32.6	25.4	7.06 (.01)	1.67 (.21)
Frequency dyspnea limits activities (0-18)	6.5	7.1	5.8	3.6	3.64 (.07)	6.83 (.01)
Pain‡						
Worst (0-10)	5.5	5.6	5.9	4.8	0.05 (.83)	1.31 (.26)
Least (0-10)	3.9	2.8	2.7	1.8	2.80 (.10)	0.05 (.83)
Average (0-10)	4.9	4.5	4.8	3.6	0.69 (.41)	1.03 (.32)
Right now (0-10)	3.1	2.1	3.0	2.3	0.04 (.91)	0.11 (.74)
Relief (0-100)	60.7	59.8	58.7	68.7	0.69 (.41)	1.05 (.32)
Interferes with activities (0-70)	39.9	40.8	43.1	36.4	0.006 (.94)	0.70 (.41)
Sleep§						
Sleep quality (6-24)	10.0	11.0	11.9	12.5	4.05 (.05)	0.14 (.71)
Duration (0-24 h)	6.3	6.6	6.0	5.8	2.43 (.13)	1.98 (.17)

Abbreviations: ANCOVA, analysis of covariance; time 2, 6-month evaluation; time 3, 12-month evaluation.
*Data are means adjusted for baseline values.
†Calculated using the University of California–San Diego Shortness of Breath Questionnaire.[37]
‡Calculated using the Brief Pain Inventory.[38]
§Calculated using 6 sleep items from the Medical Outcomes Study.[39]

grams (such as Meals on Wheels, home health aides, or referrals to community mental health services).

Of the 10 hospitalizations of CCT patients, the CCT was aware of 9. Hospitalized patients received at least 1 hospital visit from a team member, with a mean number of visits of 2.2 per patient. In all cases, the CCT provided information to the inpatient physicians about clinical issues or previous advance care planning decisions.

Family members of 16 (62%) of the 26 intervention patients with identified family caregivers attended at least 1 caregiver training session. Participating family members received an average of 3.6 contacts with the CCT family support nurse. The CCT chaplain contacted all intervention patients at least once. Twenty-one patients (42%) requested and received additional formal consultations with the chaplain or other religious advisors. All 50 intervention patients received at least 1 medication chart review by the CCT pharmacist. Forty-one patients (82%) received additional pharmacist consultation or education services in clinic or at home. Seventeen intervention patients (34%) attended at least 1 support group or art experiential session, and family members of 4 patients (8%) also participated in the art experiential sessions. Forty-three intervention patients (86%) received the services of a pair of volunteer medical or pharmacy student patient advocates. No volunteer was available for 7 patients. On average, advocates made 6.5 contacts per patient, including telephone calls, home visits, and hospital visits.

INTERVENTION OUTCOMES

Physical Symptoms

After controlling for the presence of dyspnea at baseline, the odds of a patient reporting any dyspnea at time 3 were significantly less for the intervention group (odds ratio, 6.07; 95% confidence interval, 1.04-35.56). Intervention patients reported significantly less dyspnea interfering with daily activities ($F=7.06$; $P=.01$) (**Table 3**). There was a significant group × time interaction with decreased limitation of activity due to dyspnea for the intervention patients but increased limitation over time for control patients ($F=6.83$; $P=.01$).

After controlling for pain at baseline, there were no statistically significant differences between groups or group × time interactions for any of the pain items (Table 3). The CCT made opioid and nonopioid pain management recommendations to PCPs in 23 cases (46%). However, in 21 of these cases (91%), no documentation that the PCP followed the recommendation could be found in the computerized medical record. The PCPs initiated a recommended opioid for only 1 (8%) of 13 patients. Although the electronic record generally does not document physician recommendations that are refused by patients, nonadherence with opioid recommendations was rare (reported by only 1 [8%] of 12 patients to whom opioids were newly prescribed).

After controlling for baseline differences, there was a statistically significant improvement in sleep quality in the intervention group ($F=4.05$; $P=.05$) (Table 3). No statistically significant differences in sleep quantity or group × time interactions emerged.

Psychosocial and Spiritual Well-being

After controlling for anxiety at baseline, there was no statistically significant group difference in mean anxiety ($P=.68$) (**Table 4**). However, anxiety scores for the intervention patients improved from times 2 to 3 (mean scores, 6.8 to 5.3), whereas those for the control patients worsened (mean scores, 5.5 to 5.9). This group × time interaction was statistically significant ($P=.05$).

After controlling for baseline depression scores, there were no significant differences between groups or sig-

©2004 American Medical Association. All rights reserved.

Downloaded From: http://archinte.jamanetwork.com/ on 05/14/2015

Table 4. Psychosocial and Spiritual Well-being of Patients in Control and Intervention Groups Over Time

	Patient Groups*					
	Control (n = 40)		Intervention (n = 50)		Statistic ANCOVA F (*P* Value)	
Symptoms (Possible Score)	Time 2	Time 3	Time 2	Time 3	Between Groups	Group × Time Interaction
Anxiety (0-24)†	5.5	5.9	6.8	5.3	0.17 (.68)	4.09 (.05)
Depression (0-60)‡	17.5	15.3	16.5	12.4	1.19 (.28)	0.71 (.40)
Spirituality§						
Overall (20-120)	91.2	92.4	98.0	105.5	8.21 (.007)	4.24 (.05)
Existential (10-60)	42.5	44.9	44.4	48.2	2.08 (.16)	0.47 (.49)
Religious (10-60)	46.4	46.4	52.2	55.6	14.01 (.001)	3.12 (.09)
Quality of life‖						
Single item (0-10)	7.0	7.1	7.6	7.5	0.94 (.34)	0.13 (.72)
Total scale score (0-100)	65.4	67.7	69.7	69.3	0.65 (.43)	1.02 (.32)
Satisfaction¶						
Satisfaction with care (20-100)	74.5	72.4	69.6	70.1	1.31 (.26)	0.61 (.44)
Attitudes toward care (4-20)	12.8	13.1	13.0	12.3	0.15 (.70)	0.82 (.37)

Abbreviations: ANCOVA, analysis of covariance; time 2, 6-month evaluation; time 3, 12-month evaluation.
*Data are means adjusted for baseline values.
†Calculated using the Profile of Mood States.[40]
‡Calculated using the Center for Epidemiological Studies Depression Scale.[41]
§Calculated using the Spiritual Well-Being Scale.[42]
‖Calculated using the Multidimensional Quality of Life Scale–Cancer Version.[43]
¶Calculated using the Group Health Association of American Consumer Satisfaction Survey.[44]

nificant group × time interactions (Table 4). For the 23 intervention patients with Center for Epidemiological Studies Depression Scale scores of at least 16 (46%), the CCT recommended antidepressant prescriptions (18 patients) or an increase in the dosage of a current antidepressant prescription (5 patients). The computerized medical record documented that an antidepressant was newly prescribed during the study period for only 3 (17%) of the 18 patients. Two patients with high Center for Epidemiological Studies Depression Scale scores refused to consider treatment with antidepressants; however, only 2 (11%) of 18 intervention patients with existing prescriptions reported nonadherence.

After controlling for baseline spiritual well-being, intervention group patients reported higher overall spiritual well-being than controls ($F=8.21$; $P=.007$) (Table 4). From times 2 to 3, the intervention group reported improved spiritual well-being (mean scores, 98.0 to 105.5), whereas the control group was unchanged (mean scores, 91.2 to 92.4). This group × time interaction was statistically significant ($F=4.24$; $P=.05$). Patients in the intervention group also scored higher on the religious subscale ($F=14.01$; $P=.001$). However, there were no group differences in scores or any significant group × time interactions on the existential subscale.

After controlling for baseline values, there were no significant quality-of-life score differences over time between groups and no statistically significant group × time interactions (Table 4).

After controlling for baseline values, there were no significant group differences or group × time interactions in health care satisfaction scores (Table 4). However, during exit interviews, intervention patients reported that the CCT improved their level of connection and satisfaction with family (30 respondents [86%]), PCPs (28 respondents [80%]), and the medical center (23 respondents [66%]).

Advance Care Planning

For the 22 intervention patients and 18 controls who had not already completed a durable power of attorney for health care at baseline, 12 intervention patients (55%) and 5 controls (28%) had completed one by time 3 ($P=.12$). For the 23 intervention patients and 19 controls who had not completed funeral arrangements at baseline, 8 intervention patients (35%) and 1 control (5%) had completed their arrangements by time 3, a statistically significant difference ($P=.03$). For the 20 intervention patients and 11 controls who had not completed plans for disposition of their possessions at baseline, 16 intervention patients (80%) and 5 controls (46%) had made plans by time 3 ($P=.11$). In exit interviews, 23 intervention patients (66%) expressed appreciation for the opportunity to discuss these and other elements of advance care planning with the CCT.

HEALTH CARE UTILIZATION AND CHARGES

On average during the study period, intervention patients made fewer visits to their PCP (mean, 7.5 vs 10.6; $P=.03$) and fewer urgent care clinic visits (mean, 0.3 vs 0.6; $P=.03$) (**Table 5**). There were no statistically significant group differences with regard to specialty clinic visits (mean, 4.9 vs 7.0; $P=.25$), emergency department visits (mean, 1.6 vs 1.7; $P=.81$), number of hospitalizations (mean, 1.2 vs 0.8; $P=.21$), or number of days hospitalized (mean, 6.3 vs 4.3; $P=.38$).

Among the 10 intervention patients who died during the study period, 5 died at home or in a nursing home, 2 died in the hospital, and 3 died in hospice care (home,

©2004 American Medical Association. All rights reserved.

Downloaded From: http://archinte.jamanetwork.com/ on 05/14/2015

Table 5. Utilization and Charges for Patients in the Control and Intervention Groups*

Characteristic	Patient Groups: Control (n = 40)	Patient Groups: Intervention (n = 50)	Statistic *t*	*P* Value
No. of medical center visits				
Clinic visits	10.6 (7.5)	7.5 (4.9)	−2.20	.03
Urgent care visits	0.6 (0.9)	0.3 (0.5)	−2.13	.04
Specialist visits	7.0 (9.1)	4.9 (8.1)	−1.16	.25
Emergency department visits	1.7 (2.8)	1.6 (2.2)	−0.24	.81
Hospital admissions	0.8 (1.0)	1.2 (2.0)	1.26	.21
Total hospital days	4.3 (9.0)	6.3 (12.4)	0.88	.38
Medical center total charges, $				
All medical center services	43 338 (69 647)	47 211 (73 009)	0.25	.80
Clinic visits	8068 (9055)	7311 (10 880)	−0.34	.73
Urgent care visits	1342 (2909)	749 (2210)	−1.06	.29
Emergency department visits	1313 (3281)	754 (1138)	−1.01	.32
Inpatient services	31 225 (66 611)	31 294 (54 285)	0.01	.10
Other charges	1427 (4714)	1619 (7973)	0.13	.89

*Unless otherwise indicated, data are mean (SD).

hospital, or institutional). Among the 5 control patients who died, 2 died at home or in a nursing home and 3 died in hospice care. There were no significant group differences with regard to location of death ($P=.40$).

The mean charge per patient for all medical center services during the study period was $47 211 (SD, $73 009) for intervention patients and $43 338 (SD, $69 647) for controls (Table 5). This difference was not statistically significant ($P=.80$). There were no significant group differences in urgent care, emergency department, or inpatient charges.

COMMENT

Our findings corroborate that patients with cancer, advanced CHF, or advanced COPD suffer significant symptoms as they near the end of life.[11,12,46] The CCT improved some, although not all, of the outcomes we examined. We found improvements in the physical (dyspnea and sleep), psychological (anxiety), spiritual (spiritual well-being), and advance care planning (funeral planning) domains. In addition, patients with access to CCT services made fewer primary care and urgent care visits, without an associated increase in specialty clinic visits, emergency department visits, number of hospitalizations, or number of days hospitalized. There were no significant group differences in medical center charges.

Study results indicate that CCT patients did not have improvements in pain, depression, or quality of life. A likely and unfortunate explanation for this finding is that the CCT's pain and depression recommendations were rarely implemented. Without appropriate treatment to relieve pain and depression, improving quality of life may be impossible.[47,48] Our research methods could not detect instances in which PCPs may have made medication recommendations that were refused by patients. However, exit interviews with intervention patients revealed that only 2 refused antidepressant medication and none refused pain medications. These findings suggest that PCPs ignored important advice and are consistent with previous studies documenting PCP reluctance to treat pain and depression as a barrier to good care.[11,46,49-53] It is also possible that PCPs did not follow CCT recommendations because patients underwent assessment by a social worker with physician review, rather than direct examination by a physician. However, the CCT consultation letter to PCPs was written and signed by a physician.

Overall, the CCT was most effective in improving outcomes that the team could influence directly, via provision of services, education, and support. Although supplemental oxygen therapy was frequently recommended, even dyspnea may have improved because of CCT attention to patients' anxiety and fear about shortness of breath.[54,55] The CCT had little effect on outcomes that required action by PCPs, reflecting a limitation of consultation services in general.[1,56] Outpatient palliative medicine teams might have greater efficacy if they are able to directly implement recommendations within clearly defined limits agreed to by the PCP.

There was no significant difference in mortality or location of death between the groups, or any evidence that intervention patients enrolled in hospice care more frequently. In general, these outpatients with advanced illness received palliation of symptoms while pursuing aggressive treatment of their disease.

Our findings have several limitations. First, participants were not individually randomized. However, nearly all baseline characteristics in the 2 groups were similar. Rather than randomize patients within a single practice, 2 similar but separate subpopulations of patients and physicians were randomly assigned to the intervention and control arms (ie, those in 2 discrete practice modules). We chose this design to eliminate the contamination that would have occurred if physicians had cared for both intervention and control patients. Because physicians of patients in the intervention group did not simultaneously care for control patients, we decreased the risk for con-

©2004 American Medical Association. All rights reserved.

Downloaded From: http://archinte.jamanetwork.com/ on 05/14/2015

tamination whereby control group patients might indirectly receive the influence of CCT consultations and physician education.

Second, although well matched at baseline along most sociodemographic, functional, disease severity, and outcome measurements, the intervention group had more women. It is not clear, however, that improvement in dyspnea, anxiety, or spiritual well-being is more likely in women than men, so this difference is unlikely to confound our results, particularly since we controlled for baseline outcome values.

Third, exit interviews may have been limited by acquiescence bias. Patients may have inflated positive feedback about the CCT because of their relationship with the interviewing social worker. However, the fact that only some outcomes were improved argues against more than a minor contribution of this bias to our results. In addition, exit interviews were conducted only with patients completing the intervention. It is possible that patients who failed to complete the study might have felt differently about their CCT experience. However, available information suggests that those who did not complete the study were similar to those who did.

Fourth, the sample studied here was small, allowing for the possibility of type II errors. However, our a priori power calculation showed that our sample size was sufficient to detect a clinically meaningful difference in pain scores. In addition, despite statistically significant differences in survey scores, some findings (such as sleep quality differences) may not be clinically meaningful or have only a small effect size. However, in the cases of anxiety and dyspnea, not only were the differences clinically meaningful, but the intervention group improved while the control group worsened. We also consider the spiritual well-being and advance care planning differences observed to be clinically significant.

Fifth, our study collected basic charge data only and did not include a formal cost-benefit analysis. Decreased primary care and urgent care visits were not accompanied by increased utilization of other medical center services, but this decrease in clinic visits was not large enough to result in a statistically significant difference in overall charges between groups. Data on medication, out-of-pocket, and outside hospitalization charges were not collected; however, little care was received outside the medical center by these patients. Precise intervention costs were impossible to extract for a formal cost-benefit analysis, as research and clinical intervention costs were enmeshed in this study. However, we estimate the cost of the intervention to be modest, consisting primarily of part-time social worker effort.[24] Now that we have some evidence of intervention efficacy, future research should assess the real costs of the intervention. Such an assessment would need to include careful accounting of the costs of all personnel time and activities (including patient care, chart review, team meeting, PCP communication, and administrative time), medications, intervention administration, medical equipment and supplies, and patient out-of-pocket expenses.

Finally, even for the benefits shown, the results may not be generalizable to patients with diseases other than CHF, COPD, or cancer, or to patients in different clinical settings, although our patients seem typical of those with chronic medical conditions. Also, because of the relatively large number of eligible patients refusing to enroll, the results may not apply to the population of patients with these diseases who are unable to participate or uninterested in participating in such an intervention. However, the study refusal rate was similar in the intervention and control groups, and both groups offered similar reasons for refusing to participate.

Nonetheless, our results justify a larger, randomized controlled trial, including methods to increase PCP adherence to recommendations, or perhaps a comanagement model in which the CCT physicians can prescribe medications for patients, as is the case for other subspecialty consultations. Future studies should determine (1) which specific elements of the service actually led to the identified improvements, (2) the cost-effectiveness of such interventions, and (3) whether even earlier palliative medicine intervention would offer similar benefits.

The CCT trial demonstrated that a palliative medicine consultation service for outpatients can improve patient outcomes in the domains where it has a direct impact on patient care. Greater benefits could be achieved if consultants assumed earlier and more direct management of palliative care issues, including prescribing appropriate medications. Ultimately, we must attend to the needs of our aging population in which an increasing number of people are living fully even as they near the end of life. Patients with advanced chronic illness clearly desire palliative care, even as they pursue treatment of disease. However, since one fifth of the study patients died during the intervention year, physicians may have less time than they think to provide it.

Accepted for publication February 20, 2003.

This study was supported by grant 035486 from the Robert Wood Johnson Foundation, Princeton, NJ.

We wish to thank the patients and families participating in the CCT project and the dedicated members of the CCT, including Celi Adams, RN, Ronald Finley, PharmD, Cindy Perlis, MFA, Jane Petersen, Jason Satterfield, PhD, Karen Schanche, MSW, and Rodney Seeger, MDiv. We also thank Melanie Merriman, PhD, MBA, and Amy J. Markowitz, JD, for their editorial suggestions, and offer our deepest respect and appreciation for the leadership and support of Ira Byock, MD, and Jeannie Twohig, MPA, of the Promoting Excellence in End-of-Life Care National Program office, Missoula, Mont, and Rosemary Gibson, MSc, of the Robert Wood Johnson Foundation.

Corresponding author and reprints: Michael W. Rabow, MD, Department of Medicine, University of California, San Francisco/Mount Zion, 1701 Divisadero St, Fifth Floor, San Francisco, CA 94115 (e-mail: mrabow@medicine.ucsf.edu).

REFERENCES

1. The SUPPORT Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: the Study to Understand Prognoses and Preference for Outcomes and Risks of Treatments (SUPPORT) [published correction appears in *JAMA*. 1996;275:1232]. *JAMA*. 1995;274:1591-1598.
2. Committee on Care at the End of Life, Institute of Medicine. *Approaching Death: Improving Care at the End of Life*. Washington, DC: National Academy Press; 1997.

©2004 American Medical Association. All rights reserved.

Downloaded From: http://archinte.jamanetwork.com/ on 05/14/2015

3. Cassell CK, Foley KM. *Principles for Care of Patients at the End-of-Life: An Emerging Consensus Among Specialties of Medicine.* New York, NY: Millbank Memorial Fund; 1999.
4. Gibson R. The Robert Wood Johnson Foundation grant-making strategies to improve care at the end of life. *J Palliat Med.* 1998;1:415-417.
5. Lynn J, O'Connonr MA, Dulac JD, Roach MJ, Ross CS, Wasson JH. MediCaring: development and test marketing of a supportive care benefit for older people. *J Am Geriatr Soc.* 1999;47:1058-1064.
6. Steinhauser KE, Christakis NA, Clipp EC, McNeilly M, McIntyre L, Tulsky JA. Factors considered important at the end of life by patients, family, physicians, and other care providers. *JAMA.* 2000;284:2476-2482.
7. Task Force on Palliative Care, Last Acts Committee. *Precepts of Palliative Care.* Princeton, NJ: Robert Wood Johnson Foundation; 1997.
8. Christakis NA, Escarce JJ. Survival of Medicare patients after enrollment in hospice programs. *N Engl J Med.* 1996;335:172-178.
9. Lynn J. Serving patients who may die soon and their families: the role of hospice and other services. *JAMA.* 2001;285:925-932.
10. Fox E, Landrum-McNiff K, Zhong Z, Dawson NV, Wu AW, Lynn J. Evaluation of prognostic criteria for determining hospice eligibility in patients with advanced lung, heart, or liver disease. *JAMA.* 1999;282:1638-1645.
11. Claessens MT, Lynn J, Xhong Z, et al. Dying with lung cancer or chronic obstructive pulmonary disease: insights from SUPPORT. *J Am Geriatr Soc.* 2000; 48(suppl):S146-S153.
12. Levenson JW, McCarthy EP, Lynn J, Davis RB, Phillips RS. The last six months of life for patients with congestive heart failure. *J Am Geriatr Soc.* 2000;48(suppl): S101-S109.
13. Lynn J. Caring at the end of our lives. *N Engl J Med.* 1996;335:201-202.
14. Bascom PB. A hospital-based comfort care team: consultation for seriously ill and dying patients. *Am J Hosp Palliat Care.* 1997;14:57-60.
15. Jecker NS, Self DJ. Separating care and cure: an analysis of historical and contemporary images of nursing and medicine. *J Med Philos.* 1991;16:285-306.
16. Healthcare Demand and Disease Management. Complex chronic care patients managed using hospice model. *Healthc Demand Dis Manag.* 1998;4:39-42.
17. Espe P, Hampton JN, Finn J, Smith DC, Regiani S, Pienta KJ. A new concept in cancer care: the supportive care program. *Am J Hosp Palliat Care.* 1999;16:713-722.
18. Von Gunten CF. Secondary and tertiary palliative care in US hospitals. *JAMA.* 2002;287:875-881.
19. Gazelle G, Buxbaum R, Daniels E. The development of a palliative care program for managed care patients: a case example. *J Am Geriatr Soc.* 2001;49:1241-1248.
20. Walsh D. The Harry R. Horvitz Center for Palliative Medicine (1987-1999): development of a novel comprehensive integrated program. *Am J Hosp Palliat Care.* 2001;18:239-250.
21. Abraham JL, Callahan J, Rossetti K, Pierre L. The impact of a hospice consultation team on the care of veterans with advanced cancer. *J Pain Symptom Manage.* 1996;12:23-31.
22. Boult C, Boult LB, Morishita L, Dowd B, Kane RL, Urdangarin CF. A randomized clinical trial of outpatient geriatric evaluation and management. *J Am Geriatr Soc.* 2001;49:351-359.
23. Quaglietti SE, Atwood JE, Ackerman L, Froelicher V. Management of the patient with congestive heart failure using outpatient, home, and palliative care. *Prog Cardiovasc Dis.* 2000;43:259-274.
24. Rabow MW, Petersen JJ, Schanche K, Dibble SL, McPhee SJ. The Comprehensive Care Team: a description of a controlled trial of care at the beginning of the end of life. *J Palliat Med.* 2003;6:489-499.
25. Steinhauser KE, Christakis NA, Clipp EC, et al. Preparing for the end of life: preferences of patients, families, physicians, and other care providers. *J Pain Symptom Manage.* 2001;22:727-737.
26. Powazki Rd, Palcisco C, Richardson M, Stagno SJ. Psychosocial care in advanced cancer. *Semin Oncol.* 2000;27:101-108.
27. Sheldon FM. Dimensions of the role of the social worker in palliative care. *Palliat Med.* 2000;14:491-498.
28. Hearn J, Higginson JJ. Do specialist palliative care teams improve outcomes for cancer patients? a systematic literature review. *Palliat Med.* 1998;12:317-332.
29. Ferguson JA, Weinberger M. Case management programs in primary care. *J Gen Intern Med.* 1998;13:123-126.
30. Rich MW, Beckham V, Wittenberg C, Leven CL, Freedland KE, Carney RM. A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. *N Engl J Med.* 1995;333:1190-1195.
31. Ellrodt G, Cook DJ, Lee J, Cho M, Hunt D, Weingarten S. Evidence-based disease management. *JAMA.* 1997;278:1687-1692.
32. Kennett CE. Participation in a creative arts project can foster hope in a hospice day centre. *Palliat Med.* 2000;14:419-425.
33. Curd PR. Advance care planning reconsidered: toward an operational definition of outpatient advance care planning. *J Palliat Med.* 1999;2:157-159.
34. Detmar SB, Muller MJ, Wever LD, Schornagel JH, Aaronson NK. The patient-physician relationship: patient-physician communication during outpatient palliative treatment visits: an observational study. *JAMA.* 2001;285:1351-1357.
35. Rabow MW, Petersen JJ, Schanche K. Volunteer patient advocacy: an interdisciplinary course on attending to patients at the end of life. *J Palliat Med.* 2002; 5:754-755.
36. Linn MW, Linn BS. The Rapid Disability Rating Scale-2. *J Am Geriatr Soc.* 1982; 30:378-382.
37. Eakin EG, Resnikoff PM, Prewitt LM, Ries AL, Kaplan RM. Validation of a new dyspnea measure: the UCSD Shortness of Breath questionnaire. *Chest.* 1998; 113:619-624.
38. Cleeland CS, Ryan KM: Pain assessment: global use of the Brief Pain Inventory. *Ann Acad Med Singapore.* 1994;23:129-138.
39. McHorney CA, Ware JE, Rogers W, Raczek AB, Lu JFR. The validity and relative precision of MOS Short- and Long-Form Health Status Scales and Dartmouth COOP Charts: results from the Medical Outcomes Study. *Med Care.* 1992;30 (suppl):MS253-MS265.
40. Shacham S. A shortened version of the Profile of Mood States. *J Pers Assess.* 1983;47:305-306.
41. Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. *Appl Psychol Meas.* 1977;1:385-401.
42. Paloutzian RF, Ellison CW. Loneliness, spiritual well-being and quality of life. In: Peplau LA, ed. *Loneliness: A Sourcebook for Current Therapy.* Hoboken, NJ: John Wiley & Sons Inc; 1982:224-237.
43. Dibble SL, Padilla GV, Dodd MJ, Miaskowski C. Gender differences in the dimensions of quality of life. *Oncol Nurs Forum.* 1998;25:577-583.
44. Davies AR, Ware JE. *GHAA's Consumer Satisfaction Survey and User's Manual.* Washington, DC: Group Health Association of America; 1988.
45. CRUNCH statistical program. Oakland, Calif: CRUNCH Software Corp; 1994.
46. McCarthy EP, Phillips RS, Zhong Z, Drews RE, Lynn J. Dying with cancer: patients' function, symptoms, and care preferences as death approaches. *J Am Geriatr Soc.* 2000;48(suppl):S110-S121.
47. Jiang W, Alexander J, Christopher E, et al. Relationship of depression to increased risk of mortality and rehospitalization in patients with congestive heart failure. *Arch Intern Med.* 2001;161:1849-1856.
48. Periyakoil VS, Hallenbeck J. Identifying and managing preparatory grief and depression at the end of life. *Am Fam Physician.* 2002;65:883-890.
49. Jarrett N, Payne S, Turner P, Hillier R. "Someone to talk to" and "pain control": what people expect from a specialist palliative care team. *Palliat Med.* 1999;13:139-144.
50. Van Ede L, Yzermans CJ, Brouwer HJ. Prevalence of depression in patients with chronic pulmonary disease: a systematic review. *Thorax.* 1999;54:688-692.
51. Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in outpatients with metastatic cancer. *N Engl J Med.* 1994;330:592-596.
52. Murberg TA, Bru E, Aarsland T, Svebak S. Functional status and depression among men and women with congestive heart failure. *Int J Psychiatry Med.* 1998;28: 273-291.
53. Havranek EP, Ware MG, Lowes BD. Prevalence of depression in congestive heart failure. *Am J Cardiol.* 1999;84:348-350.
54. Luce JM, Luce JA. Perspectives on care at the close of life: management of dyspnea in patients with far-advanced lung disease: "once I lose it, it's kind of hard to catch it . . . ". *JAMA.* 2001;285:1331-1337.
55. Bruera E, Schmitz B, Pither J, Neumann CM, Hanson J. The frequency and correlates of dyspnea in patients with advanced cancer. *J Pain Symptom Manage.* 2000;19:357-362.
56. Solomon MZ. The enormity of the task: SUPPORT and changing practice. *Hastings Cent Rep.* November-December 1995;25:S28-S32.

©2004 American Medical Association. All rights reserved.

Downloaded From: http://archinte.jamanetwork.com/ on 05/14/2015