explain this observed variation in exercise-induced cognitive benefits in terms of costs and consequences.

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Financial Disclosure: None reported.
Funding/Support: The Vancouver Foundation (BCMSF, operating grant to Dr Liu-Ambrose) and the MSFHR (establishment grant to Dr Liu-Ambrose) provided funding for this study. The Canada Foundation for Innovation funded essential infrastructure used in this study (new opportunities fund to Dr Liu-Ambrose).
Trial Registration: clinicaltrials.gov Identifier: NCT00426881
Additional Information: Drs Marra and Liu-Ambrose are Michael Smith Foundation for Health Research Scholars. Dr Marra is a Canada Research Chair in Pharmaceutical Outcomes. Dr Davis is a Canadian Institutes for Health Research Canada Graduate Scholarship PhD trainee.
Additional Contributions: We thank the Vancouver South Slope YMCA management and members who enthusiastically supported the study by allowing access to participants for the training intervention and the instructors for their commitment to the participants' health and safety.

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HEALTH CARE REFORM

Hospital-Based Palliative Medicine Consultation: A Randomized Controlled Trial

Hospital-based palliative care consultation services increase patient and family satisfaction,[1,2] improve quality of life,[3] reduce intensive care unit length of stay,[4] and decrease costs.[2,5] Clear evidence of the effectiveness of palliative care consultation services in improving symptoms has been more elusive.[2,3,6] We conducted a randomized trial to evaluate the impact of a proactive palliative medicine consultation (PMC) on the care of chronically ill, hospitalized elderly patients.

Methods. The study setting was a 560-bed academic medical center. We included patients 65 years or older with heart failure, cancer, chronic obstructive pulmonary disease, or cirrhosis, who were able to give informed consent and who spoke English

This study was a randomized, prospective, clinical trial. The intervention group received a PMC on enrollment and every weekday during hospitalization. Four physicians shared PMC duties. The PMC physician saw intervention patients daily, routinely assessed symptoms and psychosocial and spiritual needs, discussed treatment preferences, and consulted a pharmacist and chaplain as needed. The PMC physician communicated findings and recommendations to the patient's team via a medical chart note and by telephone. The usual care group received a brief visit from the PMC physician who gave them a packet of information on diet and exercise.

On admission, we used the Activities of Daily Living (ADL)[7] and Instrumental Activities of Daily Living (IADL) scales[8] to categorize each subject as dependent or independent. Participants reporting the need for assistance

with any 1 of 13 tasks were categorized as dependent. We used the 15-item Geriatric Depression Scale (GDS-15) to assess depression.[9] Responses were scored 1 = "no" and "don't know" and 0 = "yes" and summed. Total scores of 6 or higher indicated the patient may be depressed. Pain, dyspnea, and anxiety were assessed daily by a research assistant who was blinded to group assignment and asked patients to rate each symptom at its worst level in the past 24 hours from 0 ("none") to 10 ("the worst you can imagine"). Patients were randomly assigned to the intervention or usual care group. All patients completed a telephone survey 2 weeks after discharge to reassess symptoms, rate physician and nursing care, and recall discussions of preferences. We reviewed medical records to determine patients' primary diagnosis on admission. This study was undertaken between January 2002 and December 2003 and approved by the University of California, San Francisco Committee on Human Research. All participants gave written informed consent.

Frequencies, means, and standard deviations were used to examine the distribution of measures. We used χ^2 analysis to test for bivariate associations between categorical variables. Repeated-measures analysis of variance was used to investigate the impact of the intervention on symptom severity over different assessment periods. We used the Statistical Package for the Social Sciences (SPSS) for Mac (version 17; SPSS Inc, Chicago, Illinois; March 11, 2009).

Results. We enrolled 107 patients (intervention, n = 54; usual care, n = 53); 81 patients (76%; intervention, n = 41; usual care, n = 40) completed follow-up surveys. Most patients were male (62%) and white (71%) and had some college education (56%). The mean (SD) age was 76 (7.5) years, and 45% were married or partnered. The primary diagnoses were heart failure (51%; mean ejection fraction, 23%); cancer (22%; type: prostate, 22%; lung, 18%; and bladder, 13%); chronic obstructive pulmonary disease (20%; mean forced expiratory volume in 1 second of 1.5 L); and cirrhosis (6%; mean Model for Endstage Liver Disease score, 16). The mean (SD) hospital length of stay was 5.5 (5.8) days. Most participants were dependant in 1 or more ADL (71%), and 21% had a GDS-IS score of 6 or higher. The groups differed in mean age (77 and 74 years in the intervention and usual care groups, respectively; $P = .007$) but not in other characteristics.

Symptom scores for all subjects improved from baseline to follow-up for pain (4.2 vs 2.3; $P < .001$), dyspnea (3.8 vs 2.0; $P < .001$), and anxiety (4.8 vs 2.4; $P < .001$). There was no additional improvement in pain ($P = .30$), dyspnea ($P = .50$), or anxiety ($P = .08$) for patients assigned to the intervention at any assessment period (**Figure**).

At follow-up, most patients believed that the staff understood what they were going through and that physicians and nurses listened to their hopes, fears, and beliefs (**Table**). However, a minority of patients reported that the physician discussed their preferences for care (43%), their chance of surviving hospitalization (42%), or their religious beliefs (31%). There were no differences between groups for any of these items.

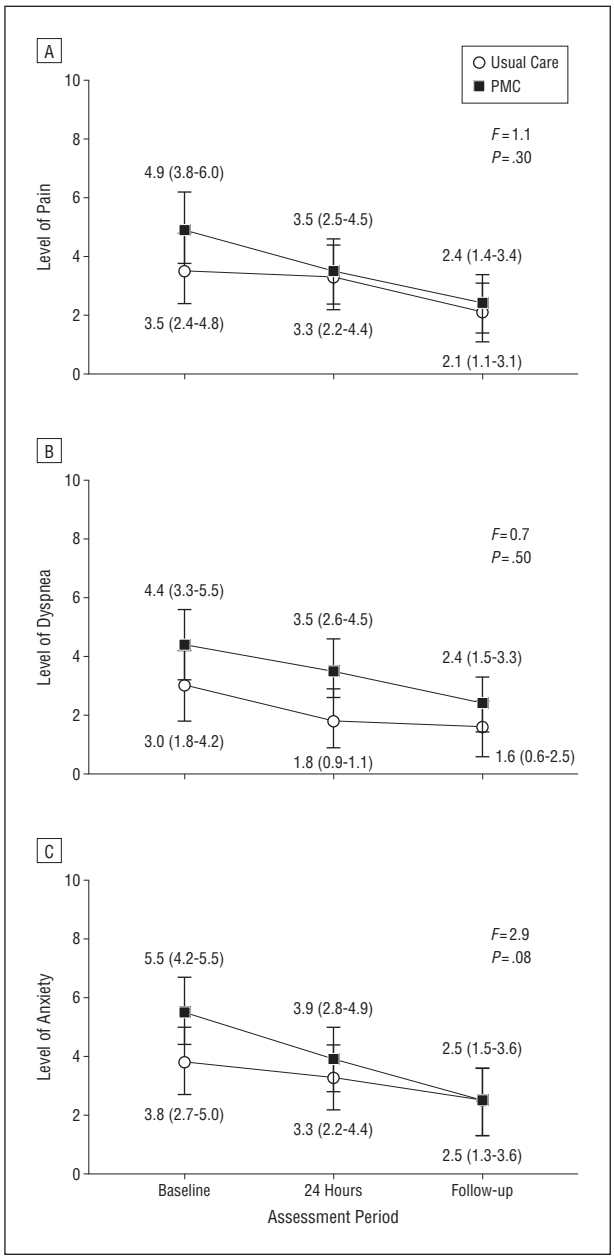

Figure. Worst pain (A), dyspnea (B), and anxiety (C) in the past 24 hours. Data are given as mean (95% confidence interval). PMC indicates palliative medicine consultation.

Comment. Consistent with previous research, our PMC intervention was not better than usual care in reducing the severity of symptoms among chronically ill inpatients. In addition, most patients in both groups rated their care highly, while only a minority of patients, even in the intervention group, reported discussions of preferences or prognosis even though such conversations were a core component of our PMC.

A number of factors may have contributed to these results. First, our subjects were not those otherwise referred for PMC and thus may have lacked issues that a PMC would affect. We thought that clinicians would resist randomizing patients they referred for PMC and therefore recruited inpatients unlikely to be referred. Despite consensus that patients at any stage of illness should re-

Table. Patient Ratings for Follow-up Questions Regarding Care, Preferences, Prognosis, and Spiritual Care Comparing Usual Care and Intervention Groups

Question	Patients, No./Total (%)		*P* Value
	Usual Care	Intervention	
Did a doctor tell you about choices for treatment? (Yes)	19/40 (48)	15/40 (38)	.50
Did you have specific wishes or plans about the types of medical treatment that you wanted? (Yes)	8/40 (20)	6/40 (15)	.80
Did a doctor talk with you about the chances that you would survive the last hospitalization? (Yes)	13/40 (33)	21/41 (51)	.11
Did someone on the health care team talk with you about your religious beliefs? (Yes)	9/39 (23)	16/41 (39)	.15
Did someone on the healthcare team suggest seeing a religious leader? (Yes)	3/38 (8)	5/40 (13)	.71
Did you feel that anyone at the hospital really understood what you and your family were going through? (Yes)	33/38 (87)	31/41 (76)	.26
Did a doctor really listen to you about your hopes, fears, and beliefs as much as you wanted? (Yes)	17/21 (81)	20/26 (77)	>.99
Did the nurses really listen to you about your hopes, fears, and beliefs as much as you wanted? (Yes)	16/18 (89)	24/27 (89)	>.99

ceive palliative care, at earlier stages palliative care may have an impact on different outcomes or require ongoing engagement.[10] Second, a truly interdisciplinary team, as we have now, may have had an impact, whereas the physician-focused PMC did not.

The following limitations temper our results. Findings from 1 institution may not be generalizable, though patients enrolled had common conditions. Although we relied on self-report measures, such reporting is standard and would not account for lack of effect. Prior descriptive and other rigorous studies have demonstrated benefits of PMC. Therefore, the lack of positive findings in our randomized trial should not dissuade clinicians from referring to a palliative care consultation service but highlights the need for further rigorously designed research to demonstrate which approach to palliative care provided to which patients would improve patient outcomes.

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Financial Disclosure: Dr Landefeld has received grants from the National Institute on Aging, the John A. Hartford Foundation, and the S. D. Bechtel Jr Foundation.

Funding/Support: This study was funded and Dr Pantilat supported by grant 1-K23-AG01018-01 from the National Institute on Aging.

Additional Contributions: We thank all patients and families who participated in this study and the PMC physicians, pharmacist, and chaplain who helped care for them. Joanne Batt, BA, Wrenn Levenberg, BA, and Emily Philipps, BA, research assistants for the Palliative Care Program at University of California, San Francisco (UCSF), contributed to the development of resources and the collection and management of data. Stephen J. McPhee, MD (UCSF), and Bernard Lo, MD (UCSF), provided input on the design of the study.

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COMMENTS AND OPINIONS

Medical Devices and the Approval Processes: United States vs France

Redberg rightly supported the plans for the new approval process from the US Food and Drug Administration (FDA) for medical devices.[1] The FDA has announced it will significantly strengthen its premarket clearance process (which is under review by the Institute of Medicine) and the process for developing and reviewing postmarket data.[1] The FDA also has announced a new transparency initiative requiring that clinical data be publicly available. Indeed, a prudent policy is warranted before approval: high-quality clinical data must show that the benefits outweigh the risks.

Sadly, the ASTRAL (Angioplasty and Stent for Renal Artery Lesions) trial will not be the last one to remind