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Effect of Palliative Care–Led Meetings for Families of Patients With Chronic Critical Illness:

A Randomized Clinical Trial

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Abstract

IMPORTANCE—Family caregivers of patients with chronic critical illness experience significant psychological distress.

OBJECTIVE—To determine whether family informational and emotional support meetings led by palliative care clinicians improve family anxiety and depression.

DESIGN, SETTING, AND PARTICIPANTS—A multicenter randomized clinical trial conducted from October 2010 through November 2014 in 4 medical intensive care units (ICUs). Adult patients (aged ≥ 21 years) requiring 7 days of mechanical ventilation were randomized and their family surrogate decision makers were enrolled in the study. Observers were blinded to group allocation for the measurement of the primary outcomes.

INTERVENTIONS—At least 2 structured family meetings led by palliative care specialists and provision of an informational brochure (intervention) compared with provision of an informational brochure and routine family meetings conducted by ICU teams (control). There were 130 patients

with 184 family surrogate decision makers in the intervention group and 126 patients with 181 family surrogate decision makers in the control group.

MAIN OUTCOMES AND MEASURES—The primary outcome was Hospital Anxiety and Depression Scale symptom score (HADS; score range, 0 [best] to 42 [worst]; minimal clinically important difference, 1.5) obtained during 3-month follow-up interviews with the surrogate decision makers. Secondary outcomes included posttraumatic stress disorder experienced by the family and measured by the Impact of Events Scale-Revised (IES-R; total score range, 0 [best] to 88 [worst]), discussion of patient preferences, hospital length of stay, and 90-day survival.

RESULTS—Among 365 family surrogate decision makers (mean age, 51 years; 71% female), 312 completed the study. At 3 months, there was no significant difference in anxiety and depression symptoms between surrogate decision makers in the intervention group and the control group (adjusted mean HADS score, 12.2 vs 11.4, respectively; between-group difference, 0.8 [95% CI, −0.9 to 2.6]; $P = .34$). Posttraumatic stress disorder symptoms were higher in the intervention group (adjusted mean IES-R score, 25.9) compared with the control group (adjusted mean IES-R score, 21.3) (between-group difference, 4.60 [95% CI, 0.01 to 9.10]; $P = .0495$). There was no difference between groups regarding the discussion of patient preferences (intervention, 75% control, 83% odds ratio, 0.63 [95% CI, 0.34 to 1.16; $P = .14$]). The median number of hospital days for patients in the intervention vs the control group (19 days vs 23 days, respectively; between-group difference, −4 days [95% CI, −6 to 3 days]; $P = .51$) and 90-day survival (hazard ratio, 0.95 [95% CI, 0.65 to 1.38], $P = .96$) were not significantly different.

CONCLUSIONS AND RELEVANCE—Among families of patients with chronic critical illness, the use of palliative care–led informational and emotional support meetings compared with usual care did not reduce anxiety or depression symptoms and may have increased posttraumatic stress disorder symptoms. These findings do not support routine or mandatory palliative care–led discussion of goals of care for all families of patients with chronic critical illness.

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Patients are considered to have developed chronic critical illness when they experience acute illness requiring prolonged mechanical ventilation or other life-sustaining therapies but neither recover nor die within days to weeks.[1] One-year survival is between 32% and 55%, and most patients require institutional care after hospital discharge.[2,3] It is estimated that chronic critical illness affected 380000 patients in the United States in 2009, accounting for health-related costs of $35 billion or 1.4% of annual US health care costs.[4]

Family members of patients in the intensive care unit (ICU) experience emotional distress including anxiety, depression, and posttraumatic stress disorder (PTSD).[5,6] Studies have shown that communication of expected outcomes in patients with chronic critical illness is often inadequate to support surrogate decision making about goals of care.[7,8] The resulting discordance between the expectations of clinicians and families can adversely affect the quality of family surrogate decision making and thus the treatment of patients with chronic critical illness.[6,9,10]

Clinical trials of interventions to improve communication about prognosis and goals of care in the ICU have shown mixed results,[11–13] and none has focused on the high-risk population

with chronic critical illness.[14] Palliative care specialists are trained to provide emotional support, share information, and engage patients and surrogate decision makers in discussions of patient values and goals of care.[15] To our knowledge, there have been no randomized clinical trials to determine if a palliative care specialist-led communication intervention for families of patients with chronic critical illness can improve both family- and patient-centered outcomes.

To address this important evidence gap, a multicenter randomized clinical trial was conducted to determine the effect of informational and emotional support meetings for families of patients with chronic critical illness led by palliative care specialists on family- and patient-centered outcomes. We hypothesized that more intensive informational and emotional support during periods of decision making would reduce symptoms of anxiety and depression in families of patients with chronic critical illness compared with the routine sharing of information and support provided by ICU teams.

Methods

The study protocol (appears in Supplement 1) was reviewed and approved by the institutional review boards at each participating hospital. The informed consent form and process fully described the nature of the intervention, and consent was obtained from all family surrogate decision makers. For patient participation, written consent was obtained from legally authorized representatives when patients were incapacitated, and informed consent was obtained from the patients when their conditions improved. The primary surrogate decision maker was determined through discussions with the ICU physicians, nurses, and social workers, by review of the medical record, and by asking individual family members. A data and safety monitoring board reviewed the outcome data at predefined intervals.

Enrollment Criteria

Patients were enrolled from an urban tertiary care center in the northeastern United States and 2 tertiary care centers and a community hospital in the southeastern United States from October 2010 through November 2014. Patients aged 21 years or older treated in medical ICUs were eligible if they required at least 7 days of mechanical ventilation uninterrupted for 96 hours or longer and were not expected to be weaned or to die within 72 hours. For the first year of the study, patients were eligible if they required at least 10 days of mechanical ventilation. Patients were identified by screening of ICU records and discussion with ICU clinicians. Patients were excluded if he or she was mechanically ventilated at an outside hospital for longer than 7 days or had chronic neuromuscular disease, trauma, or burns (eTable 1 in Supplement 2).

Patients also were excluded if a surrogate decision maker was not available or lacked English proficiency, the primary physician refused to grant permission to investigators to approach the patient or family, or the investigators were the attending physicians. Patients who were previously admitted to the study ICU or had a palliative care consultation prior to screening also were excluded. Family members were eligible if they had the responsibility of

health care decision making for the patient, which sometimes included multiple family members if they participated together in the decision-making process.

After enrollment of patients and family members, patients were randomized to the intervention or the control group using a computer-generated, web-based randomization system with blinding of allocation. The randomization was stratified by study site in block sizes varying from 8 to 10. The research coordinator at each study site who had knowledge of group assignments was not involved in collection of the primary outcomes through family interviews. A research assistant at each study site who was blinded to group assignments conducted these interviews.

Intervention

A validated and widely available brochure describing chronic critical illness was provided to the family surrogate decision makers.[16] Research coordinators then scheduled a minimum of 2 meetings with the support and information team. These teams consisted of a palliative care physician and nurse practitioner and could include social workers, chaplains, or other disciplines as needed. Study investigators did not participate as support and information team members.

The first and second support and information team meetings were separated by 10 days, targeting 2 key time points. The first meeting was conducted after 7 days of mechanical ventilation at the onset of chronic critical illness and when a tracheostomy is often considered. The second meeting was conducted after further treatment was provided for a period approximating the mean duration of mechanical ventilation after tracheostomy for patients who achieve ventilator liberation.[17] The protocol provided for scheduling of additional support and information team meetings between these time points at the request of the family, ICU physician, or support and information team clinicians.

Support and information team clinicians conducted pre-meetings with ICU physicians to review each patient's condition, prognosis, and previous discussions of goals of care (eAppendix 1 in Supplement 2). In addition to prognostic information from the ICU clinicians, support and information team clinicians also reviewed estimates of 1-year prognosis based on the ProVent 14 score.[2] The ICU clinicians could attend the support and information team meetings if desired. The support and information team meetings were structured according to a set of objectives and recommended topics[7,13,18,19] (eAppendix 2).

Support and information team clinicians were trained by reviewing the main objectives of the meeting templates that appear in the original protocol in Supplement 1; however, they were allowed some flexibility for adapting the content of the meetings to the particular needs of each family. The ICU clinicians were blinded to the structured meeting templates for the intervention group. After the meetings with family members, the support and information team provided feedback to the ICU clinicians not in attendance. The ICU clinicians held additional family meetings as per their usual practice.

Usual Care Control

The ICU clinicians managed all formal and informal family meetings per their usual practice without input from the palliative care specialists. Family surrogate decision makers in the control group received the same informational brochure (publicly available through the Society of Critical Care Medicine Website[20] and available in the study hospitals throughout the study period) as the intervention group. Clinicians were able to formally consult palliative care clinicians at their discretion even if randomized to the usual care control group, and this was encouraged if they needed assistance with symptom management or for transfer to hospice.

Data Collection

Research coordinators interviewed family surrogate decision makers prior to patient randomization to collect demographics and prehospitalization activities of daily living[21] and instrumental activities of daily living.[22] Race was self-reported using fixed categories and obtained during the interviews with family members and was measured because of its association with higher symptoms of depression.[23] Research coordinators measured fidelity to the meeting templates by completing a checklist of items covered by the end of the meeting. Investigators reviewed audio recordings for selected meetings.

Investigators periodically provided feedback on intervention fidelity to the support and information team members for quality control. Research coordinators blinded to group assignment interviewed surrogate decision makers immediately after the second support and information team meeting for the intervention group and 10 days after randomization for the control group, unless the patient had died. All surrogate decision makers were interviewed again by telephone for follow-up beginning 90 days after randomization.

Outcome Measures

The primary outcome measure was Hospital Anxiety and Depression Scale (HADS) symptom score obtained during 90-day follow-up interviews with the family surrogate decision makers.[24] The total HADS symptom score ranges from 0 (best) to 42 (worst) and there was a minimal clinically important difference of 1.5.[25] Baseline HADS scores were measured prior to randomization. Secondary outcomes included PTSD symptoms of the surrogate decision maker at 90 days measured by the Impact of Event Scale-Revised (IES-R)[26] score (range, 0 [best] to 88 [worst]).

To assess patient-focused communication about the goals of care, an advance care planning domain from a modified version of the After-Death Bereavement Family Interview[27] was used and the frequency and proportion of family members providing affirmative answers to each of the 3 yes or no questions were determined. This domain has been validated for independent administration. Although the original protocol specified 3 coprimary end points for anxiety and depression (HADS scores), PTSD (IES-R scores), and discussion of patient preferences, it was decided before enrollment that total HADS score should be the primary outcome, which is consistent with the power analysis. The trial registration reflected this change.

The dimension scores for the After-Death Bereavement Family Interview were validated for use as a group and were calculated as the sum of negative responses to individual items within each domain divided by the number of items in the domain (ie, problem score) to assess patient-focused communication regarding the goals of care. A higher problem score is an indication of more opportunities to improve care or more concerns with the quality of care. A rating from the tool to assess overall patient-focused and family-centered care also was obtained (score range, 0 [worst] to 10 [best]).

Other measures included the Quality of Communication scale[28] score (range, 0 [worst] to 10 [best]; comments marked "did not ask" were coded as 0) used for surrogate decision makers who were available in the hospital after the intervention period. Satisfaction at 90 days was assessed using the 24-item Family Satisfaction in the Intensive Care Unit survey score (range, 0 [worst] to 100 [best]).[29] Patient-focused outcomes included numbers of days of mechanical ventilation, ICU length of stay, hospital length of stay, limitations of ICU therapies (eg, mechanical ventilation, dialysis, nutrition, vasopressors), hospital mortality, and 90-day survival. Physician-surrogate discordance is not reported.

Statistical Analysis

Based on a previous study,[25] it was determined that 150 family members in the intervention group and the control group would provide a sufficient sample to detect a minimal clinically important difference of 1.5 for mean total HADS score with 90% power and a type I error of 5%. Additional patients and family surrogate decision makers were enrolled to allow for dropout and adjustment for multiple family respondents. Enrollment concluded at the end of the funded enrollment period. The HADS and IES-R scores were evaluated using hierarchical models based on the patient. For the primary analysis, the HADS score was adjusted for the baseline score and for multiple surrogate respondents. The IES-R was adjusted for multiple respondents.

In the post hoc analyses, the scores for HADS and IES-R also were adjusted for variables selected by the investigators based on their potential effects and included study site, race (white vs other), sex, and primary surrogate vs additional surrogate decision makers. The effect of patient death by the time of follow-up interviews and the effect of formal palliative care consultation were also assessed. The proportion of patients meeting diagnostic cutoffs for anxiety and depression (scores ≥ 8 for the HADS Anxiety and Depression subscales for both anxiety and depression, adjusting for baseline and for multiple surrogate respondents) and PTSD (scores >33 on the IES-R, adjusting for multiple surrogate respondents) were compared using generalized linear models allowing for random effects.

Data from the After-Death Bereavement Family Interview and Family Satisfaction in the Intensive Care Unit survey were adjusted for multiple surrogate respondents and study site. For the Quality of Communication scale, comments indicating "did not ask" were coded as 0 and a summary measure of all items was adjusted for multiple surrogate respondents, baseline score, and study site. Differences between groups for other patient outcomes were analyzed based on t tests, nonparametric tests, χ^2 tests (including the Fisher exact test), or log-rank tests as appropriate. The number of hospital days and 90-day survival rate were described using Kaplan-Meier plots. In addition, the differences between groups for 90-day

survival were described based on the Cox model. Differences in the number of hospital days were analyzed using nonparametric methods.

All analyses were 2-tailed and performed on an intent-to-treat basis. The 2-sided level of significance was set at .05. There was no adjustment of significance threshold for secondary analyses, all of which should be viewed as exploratory. Analyses were performed using SAS version 9.4 (SAS Institute Inc).

Results

Of 366 eligible patients, consent was obtained for 256, all of whom were randomized (Figure 1). There were 365 family surrogate decision makers for a mean of 1.42 per patient (median, 1.0 [range, 1–6). There were no significant differences between patients in the intervention and control groups with the exception of slightly higher independence in activities of daily living in the intervention group (Table 1). There were no significant differences between groups in the demographics of family surrogate decision makers (Table 2).

At least 1 support and information team meeting was held for 116 (89%) patients in the intervention group. Reasons for meetings not occurring included patient death or discharge prior to the scheduled meeting (n = 6) and family refusal or inability to participate (n = 8). Eighty-two percent of family surrogate decision makers in the intervention group participated in at least 1 support and information team meeting, and there was an average of 1.4 meetings per surrogate. Support and information team clinicians addressed key topics (eTable 2 in Supplement 2) suggested in the study protocol (Supplement 1); however, they were allowed to use clinical judgment to adjust the discussion to meet the needs of individual patients and families.

Patient prognosis was discussed in 100% of the first support and information team meetings and in 91% of the second meetings. Understanding by the family of the patient's values, goals, and preferences was discussed in 89% of the first support and information team meetings and in 81% of the second meetings. Physicians from the ICU attended 8.8% of the first support and information team meetings and 3.3% of the second meetings. A mean of 1.9 family meetings was conducted independently by the ICU teams for families in the intervention group after randomization that were separate from the support and information team meetings; however, this was not significantly different than the number of family meetings (mean, 2.1 meetings) conducted by the ICU teams for families in the control group (between-group difference, −0.2 meetings; 95% CI, −0.6 to 0.2 meetings).

Final interviews were completed for 312 family surrogate decision makers (85%) at a median of 105 days after randomization. There was no significant difference in the mean adjusted total HADS score at 3 months between the intervention group (12.2) and the control group (11.4; between-group difference, 0.8 [95% CI, −0.9 to 2.6], *P* = .34; Table 3). Adjusting for additional variables including study site, race, sex, primary surrogate, and patient death did not affect the difference in a meaningful way. Thirteen percent of patients in the intervention group had a formal palliative care consultation outside the study protocol

compared with 22% of patients in the control group; however, adjusting for this variable had no significant effect on the between-group comparison. Limiting the analysis to those family members who participated in a support and information team meeting in the intervention group had no significant effect.

Symptoms of PTSD measured by the adjusted mean total IES-R score were significantly higher in the intervention group (25.9) compared with the control group (21.3) (between-group difference, 4.60 [95% CI, 0.01 to 9.10], *P* = .0495; Table 3).Mean scores were significantly higher for the Avoidance subscale in the intervention group (8.8) compared with the control group (7.1; between-group difference, 1.70 [95% CI, 0.02 to 3.30], *P* = .048) and for the Hyperarousal subscale (5.9 for the intervention group vs 4.4 for the control group; between-group difference, 1.5 [95% CI, 0.1 to 2.8], *P* = .03). Conversely, the mean Intrusion subscale score was not significantly different for the intervention group (11.1) compared with the control group (9.7; between-group difference, 1.4 [95% CI, −0.6 to 3.4]; *P* = .17).

Adjusting for additional covariates in the post hoc analyses did not have a meaningful effect on the between-group differences (Table 3). Limiting the analysis to family members in the intervention group who received at least 1 support and information team meeting did not have a significant effect. Differences in the proportion of family decision makers who met a diagnostic cutoff for PTSD were not statistically significant (34% in the intervention group vs 25% in the control group; odds ratio, 1.56 [95% CI, 0.90–2.60], *P* = .10).

For the main patient-focused communication outcome measure, nearly all family surrogate decision makers in both groups indicated that medical treatments and procedures had been discussed and were consistent with the wishes of the patients (Table 4). The proportion answering in the affirmative to all 3 preference measure questions (Did physician discuss patient wishes about medical treatment? Did physician discuss if care was consistent with patient wishes? Were all medical procedures and treatments consistent with patient wishes?) was not significantly different (75% of the intervention group vs 83% of the control group; odds ratio, 0.63 [95% CI, 0.34 to 1.16], *P* = .14) when adjusting for multiple respondents and study site. There were no significant differences in any other dimension of the After-Death Bereaved Family Interview (Table 4).

The median summary measure on the Quality of Communication scale (after adjusting for multiple family member surrogate decision makers, baseline score, and study site) was not significantly different between groups (8.05 for the intervention group vs 7.76 for the control group; between-group difference, 0.29 [95% CI, −0.63 to 1.21], *P* = .40). The mean scores on the Family Satisfaction in the Intensive Care Unit survey were not significantly different (81.1 for the intervention group vs 84.3 for the control group; between-group difference, −3.1 [95% CI, −7.3 to 1.0], *P* = .13; Table 4).

The median number of hospital days after randomization was not significantly different between the groups (19 days for the intervention group vs 23 days for the control group; between-group difference, −4 days [95% CI, −6 to 3 days], *P* = .51; Table 5 and Figure 2). Ninety-day follow-up was completed for all but 2 patients (99%) and 90-day survival was

not significantly different between groups (hazard ratio, 0.95 [95% CI, 0.65 to 1.38], *P* = .96; Figure 2). Post hoc adjustment for baseline activities of daily living and study site did not alter the outcome (hazard ratio, 1.01 [95% CI, 0.69 to 1.47], *P* = .96). There were no significant between-group differences for other patient outcomes including duration of mechanical ventilation, ICU length of stay, limitation of ICU treatments, and discharge disposition (Table 5).

Discussion

To our knowledge, this is the first multicenter randomized trial of a palliative care clinician-based, informational, and emotional support intervention for family surrogate decision makers of patients with chronic critical illness. Protocol-based informational and emotional support meetings with palliative care specialists did not improve anxiety or depression symptoms among family surrogate decision makers at 3 months. Exploratory analyses indicate that the intervention may have increased PTSD symptoms. In addition, there was no significant effect on the patient and resource outcomes of duration of mechanical ventilation and hospital length of stay and there was no effect on survival.

Potential explanations for this lack of benefit may relate to the high perceptions of quality of communication, emotional support, and family satisfaction in the usual care control. When informational support provided by the primary team is sufficient, additional focus on prognosis may not help and could further upset a distressed family, even when emotional support is concurrently provided. Some early interventions (such as debriefing) intended to mitigate a major psychological trauma in other contexts may have paradoxically resulted in exacerbation of symptoms of PTSD at longer-term follow-up.[30]

Alternatively, the intervention may have been insufficient to overcome the high levels of family stress associated with having a relative with chronic critical illness. The support and information team intervention focused on providing informational and emotional support according to the study protocol for a sequence of 2 meetings. Support and information team clinicians may not have communicated qualitatively or quantitatively in the same way as they do in their regular palliative care consultations outside the research context; however, they were free to adapt their approach as needed for individual circumstances. The fidelity rate for some items on the meeting template suggests that they did indeed adapt freely.

It is also possible that the intervention was limited in its ability to have an effect on outcomes because it did not consistently provide continuity between admitting services and hospital units, or it lacked the full array of palliative care services, including more frequent support visits by team members, symptom management, and the added expertise of other disciplines, such as social work or chaplaincy. In addition, the absence of direct participation by ICU clinicians in most support and information team meetings could have created a discordance in communication with families that offset the positive effects of these meetings.

In the literature of ICU communication interventions, 1 randomized trial conducted in France,[13] which included a family meeting and an informational brochure for families of

patients at the time of withdrawal of life-sustaining therapies, showed significant improvement in anxiety, depression, and PTSD symptoms. The intervention in this trial enrolled families earlier in the decision-making process, representing a distinctly different clinical situation.

Another trial that tested whether communication skills training for residents and nurse practitioners could improve family outcomes did not improve the quality of communication and was associated with increased depression symptoms.[11] A trial that enrolled general patients in the ICU and involved trained communication facilitators as the intervention did not show a benefit in the level of family depression symptoms at 3 months but did show a benefit at 6 months; however, there were no effects on anxiety and PTSD.[12] A lower follow-up rate in that study could have introduced more response bias. Their results did show significant decreases in hospital length of stay for decedents. Decision making about continued intensive care for patients with chronic critical illness, all of whom have survived the acute phase of illness, may present greater challenges for successful interventions. Communication interventions that occur earlier rather than after 7 days of mechanical ventilation or that are more intensive might be required.

Chronic critical illness has been recommended as a trigger for specialist palliative care consultation to facilitate discussions regarding the goals of care.[31–33] However, palliative care personnel are facing increasing clinical demands as the need for palliative services outpaces the rate of clinician training.[34,35] Results of this trial indicate that routinely allocating scarce palliative care resources toward this large patient population may be ineffective if the interaction is limited to only 1 to 2 meetings. This does not mean that palliative consultation is not warranted in the support and communication for families of patients with chronic critical illness when particularly challenging cases arise or when assistance is needed for symptom management or hospital discharge disposition planning. Future research on communication interventions in the ICU should focus on identifying individual family decision makers who are at highest risk for poor emotional outcomes and targeting palliative care interventions to their specific needs. Interventions can include training and support to enhance primary palliative care by ICU clinicians.[36,37]

The multicenter randomized design, the variety of enrollment study sites, and the high participation and completion rates are strengths of this study, particularly considering the complex patient conditions and emotional states of families with patients being treated in the ICU.

Study limitations include the impossibility of blinding families to the intervention. However, research personnel conducting interviews were blinded to study group allocation, and bias would most likely favor the intervention, an unlikely occurrence given the findings. Although a halo effect or control group contamination could have biased the study toward the null, members of the ICU teams attended less than 10% of the support and information team meetings, and eligible patients were not enrolled when the investigators were providing care for them.

Conclusions

Among families of patients with chronic critical illness, the use of palliative care–led informational and emotional support meetings compared with usual care did not reduce anxiety or depression symptoms and may have increased PTSD symptoms. These findings do not support routine or mandatory palliative care–led discussion of goals of care for all families of patients with chronic critical illness.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Key Points

Question

Do palliative care–led informational and emotional support meetings improve anxiety and depression symptoms for family decision makers of patients with chronic critical illness vs usual care and communication by ICU clinicians?

Findings

In this randomized clinical trial that included 365 family decision makers for 256 adult patients, family symptom scores for anxiety and depression were 12.2 for the intervention and 11.4 for usual care, a difference that was not significant.

Meaning

Palliative care–led information and support meetings for discussion of goals of care do not need to be routinely conducted for all family decision makers of patients with chronic critical illness.
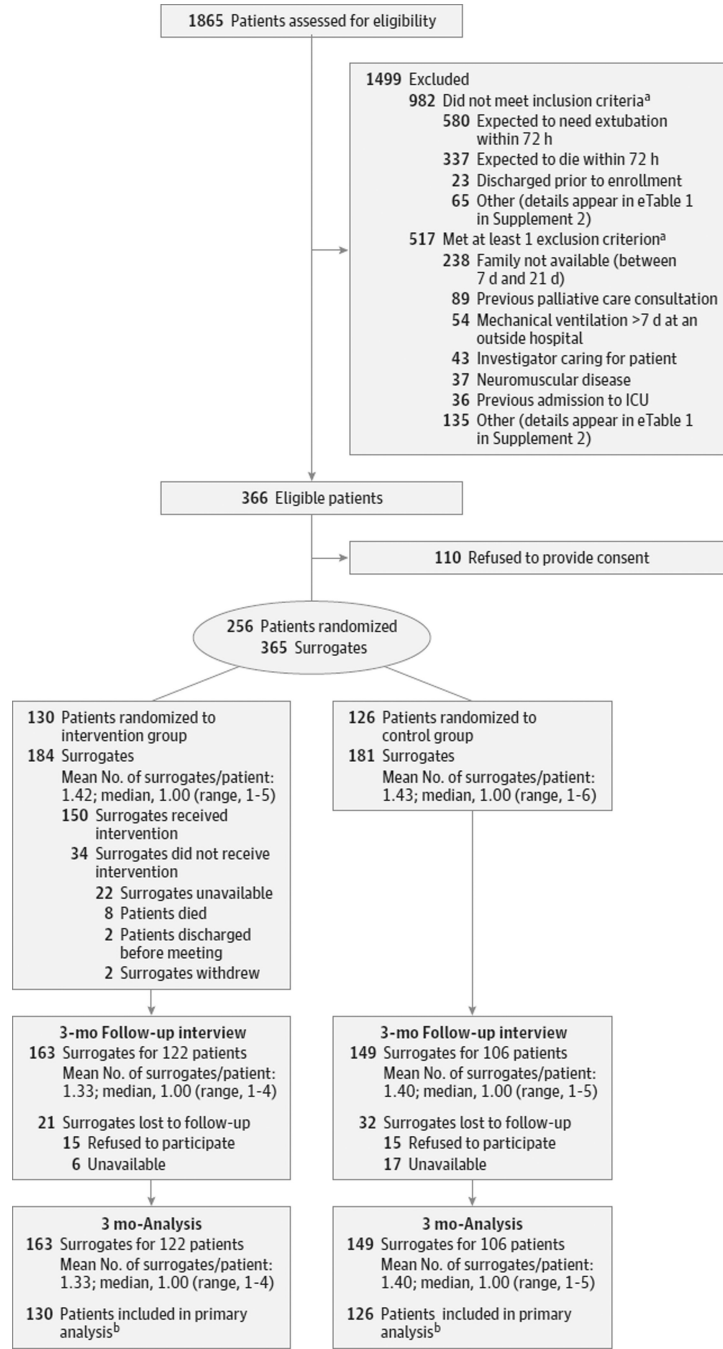
Figure 1. Flow of Patients and Family Surrogate Decision Makers
[a] Patients may meet more than 1 criterion.
[b] Patient outcome data available when surrogates withdrew or were lost to follow-up.
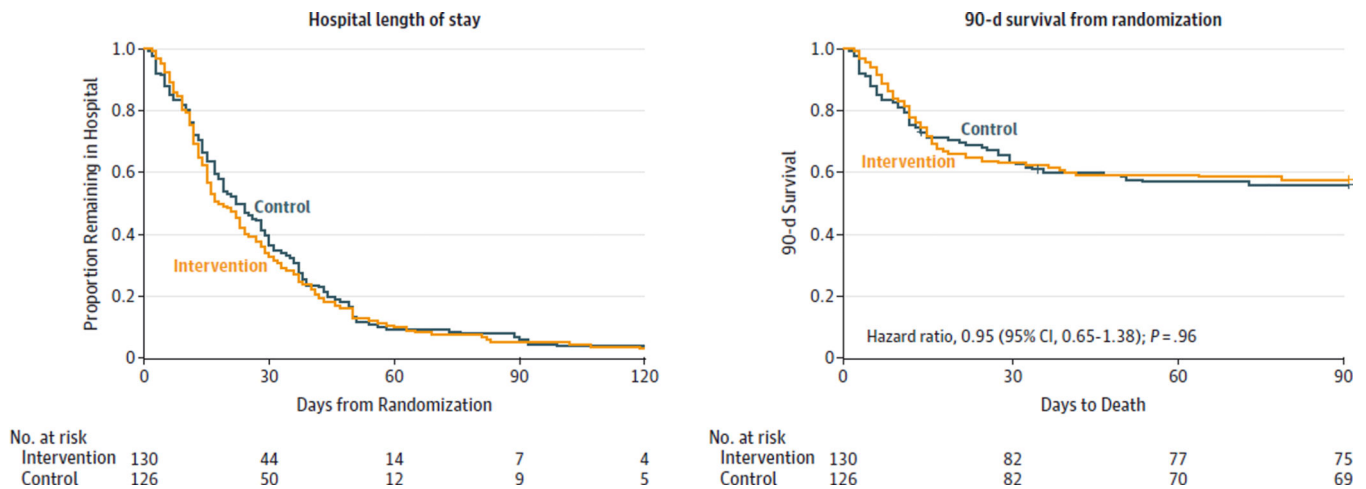
Figure 2. Kaplan-Meier Plot of Patient Hospital Length of Stay After Randomization and 90-Day Survival

The median hospital length of stay was 19 days (interquartile range, 12 to 37 days) for the intervention group compared with 23 days (interquartile range, 12 to 39 days) for the control group (between-group difference, –4 days [95%CI, –6 to 3 days]; *P* = .51). For 90-day survival, the cross-hatches indicate censored events.

Table 1

Baseline Characteristics of Patients

| Characteristic	Patients[a]	
	Intervention Group (n = 130)	Control Group (n = 126)
Age, mean (95% CI), y	58 (55.2–60.8)	57 (54.0–59.7)
Female sex, No. (%)	66 (51)	65 (52)
Ethnicity, No. (%)		
Hispanic or Latino	17 (13)	15 (12)
Non-Hispanic or Non-Latino	112 (87)	111 (88)
Race, No. (%)		
Black	32 (25)	31 (25)
American Indian/Alaskan Native	1 (1)	4 (3)
Asian	6 (5)	3 (2)
White	79 (61)	79 (63)
Missing	11 (9)	9 (7)
Religion, No. (%)		
Catholic	29 (23)	22 (18)
Protestant	42 (33)	38 (30)
Jewish	8 (6)	8 (6)
Muslim	2 (2)	1 (1)
None	9 (7)	6 (5)
Other	38 (30)	51 (41)
Insurance, No. (%)		
Medicare	60 (46)	57 (45)
Medicaid	11 (8)	16 (13)
Commercial	47 (36)	36 (29)
None	9 (7)	11 (9)
Other	3 (2)	6 (5)
Study site, No. (%)		
Mount Sinai Medical Center	43 (33)	41 (33)
University of North Carolina Hospitals	43 (33)	41 (33)
Duke University Medical Center	23 (18)	23 (18)
Duke Regional Hospital	21 (16)	21 (17)
Activities of daily living score,[21] mean (95% CI)[b]	5.1 (4.8–5.4)	4.5 (4.1–4.8)
Instrumental activities of daily living score,[22] mean (95% CI)[c]	5.4 (5.0–5.9)	5.0 (4.5–5.5)
Chronic comorbidities, mean No./patient (95% CI)	2.2 (1.9–2.4)	2.2 (1.8–2.5)
Acute comorbidities, mean No./patient (95% CI)	2.3 (2.0–2.6)	2.6 (2.3–2.9)
APACHE II score at enrollment, mean (95% CI)	26.2 (25.2–27.3)	25.8 (24.6–27.0)

Characteristic	Patients[a]	
	Intervention Group (n = 130)	Control Group (n = 126)
ProVent 14 score,[2] mean (95% CI)[d]	2.7 (2.5–3.0)	2.6 (2.4–2.8)
Predicted 1-y mortality, mean % (95% CI)	59 (54.2–63.3)	55 (50.7–60.2)
Renal replacement therapy during hospitalization, No. (%)	40 (31)	38 (30)
Vasopressors during hospitalization, No. (%)	106 (82)	99 (79)
Had advance directive at enrollment, No. (%)	14 (11)	18 (14)
Cardiopulmonary resuscitation preference at enrollment, No. (%)		
Perform it	118 (91)	115 (91)
Forego it	12 (9)	11 (9)
No. of surrogate decision makers per patient, No. (%)		
1 (primary decision maker only)	89 (68)	88 (70)
2 (primary plus 1 additional)	31 (24)	29 (23)
>2 (primary plus multiple additional ones)	10 (8)	9 (7)

Abbreviation: APACHE, Acute Physiologic Assessment and Chronic Health Evaluation.

[a]Not all percentages sum to 100 due to rounding.

[b]The range is 0 (dependent) to 6 (independent) in 6 activities.

[c]The range is 0 (dependent) to 8 (independent) in 8 activities.

[d]The range is 0 (low risk of 1-year mortality) to 6 (high risk of 1-year mortality).

Table 2

Baseline Characteristics of Surrogate Decision Makers

Characteristic	Surrogate Decision Makers[a]	
	Intervention Group (n = 184)	Control Group (n = 181)
Age, mean (95% CI), y	51 (48.8–52.8)	51 (48.6–52.7)
Female sex, No. (%)	128 (70)	131 (72)
Ethnicity, No. (%)		
Hispanic or Latino	28 (15)	23 (13)
Non-Hispanic or Non-Latino	155 (85)	158 (87)
Marital status, No. (%)		
Married	108 (59)	120 (66)
Separated	10 (5)	7 (4)
Divorced	15 (8)	16 (9)
Widowed	33 (18)	29 (16)
Single	11 (6)	4 (2)
Missing	7 (4)	5 (3)
Primary surrogate's relationship to patient, No. (%)		
Child (age >18 y)	41 (32)	41 (33)
Parent	18 (14)	17 (13)
Sibling	11 (8)	15 (12)
Spouse or partner	57 (44)	47 (37)
Other	3 (2)	6 (5)
Employment, No. (%)		
Employed	103 (57)	93 (51)
Unemployed (not disabled)	15 (8)	22 (12)
Homemaker	10 (6)	16 (9)
Retired	40 (22)	25 (14)
Disabled	13 (7)	22 (12)
Student	1 (1)	3 (2)
Treated for anxiety in the past, No. (%)	38 (21)	45 (25)
Treated for depression in the past, No. (%)	54 (29)	53 (29)
No. of surrogate decision makers by study site		
Mount Sinai Medical Center	62 (34)	53 (29)
University of North Carolina Hospitals	58 (32)	57 (32)
Duke University Medical Center	30 (16)	37 (20)
Duke Regional Hospital	34 (18)	34 (19)
Hospital Anxiety and Depression Scale unadjusted score at baseline, mean (SD)		
Total[b]	16.0 (8.1)	16.4 (8.4)

Characteristic	Surrogate Decision Makers[a]	
	Intervention Group (n = 184)	Control Group (n = 181)
Anxiety subscale[c]	9.5 (4.8)	9.8 (4.7)
Depression subscale[c]	6.6 (4.0)	6.7 (4.4)

[a] Each surrogate decision maker enrolled (primary and additional ones). Not all percentages sum to 100 due to rounding.

[b] The range is 0 (best) to 42 (worst) and the minimal clinically important difference is 1.5.

[c] The range is 0 (best) to 21 (worst).

Table 3

Outcomes Measured at 3 Months for Surrogate Decision Makers

	Surrogate Decision Makers		Difference Between Groups, Mean (95% CI)	*P* Value
	Intervention Group	Control Group		
Hospital Anxiety and Depression Scale (HADS) Score at 3 mo[a]				
No. of surrogate decision makers	163	149		
Total unadjusted, mean (SD)	12.1 (8.0)	11.4 (8.6)		
Adjusted, mean (95% CI)				
Baseline and multiple respondents	12.2 (11.0 to 13.4)	11.4 (10.1 to 12.6)	0.8 (−0.9 to 2.6)	.34
Baseline, multiple respondents, and study site	12.2 (11.0 to 13.4)	11.4 (10.2 to 12.6)	0.8 (−1.0 to 2.5)	.38
Baseline, multiple respondents, study site, race, sex, and primary or additional surrogate	11.8 (10.4 to 13.2)	11.1 (9.7 to 12.5)	0.7 (−1.0 to 2.5)	.41
Baseline, multiple respondents, study site, race, sex, primary or additional surrogate, and patient death by time of interview	12.0 (10.6 to 13.4)	11.4 (10.0 to 12.8)	0.7 (−1.1 to 2.4)	.45
HADS Anxiety Subscale Score at 3 mo[b]				
No. of surrogate decision makers	163	149		
Total unadjusted, mean (SD)	7.2 (4.6)	6.4 (4.7)		
Adjusted, mean (95% CI)				
Baseline and multiple respondents	7.2 (6.6 to 7.9)	6.4 (5.7 to 7.1)	0.8 (−0.1 to 1.8)	.09
Baseline, multiple respondents, and study site	7.2 (6.5 to 7.9)	6.4 (5.7 to 7.1)	0.8 (−0.2 to 1.8)	.11
Baseline, multiple respondents, study site, race, sex, and primary or additional surrogate	7.3 (6.5 to 8.1)	6.5 (5.7 to 7.3)	0.8 (−0.2 to 1.8)	.12
Consistent with anxiety (score 8), adjusted for baseline and multiple respondents, % (95% CI)	44 (35 to 53)	31 (23 to 40)	1.72 (1.00 to 3.00)[c]	.05
HADS Depression Subscale Score at 3 mo[b]				
No. of surrogate decision makers	163	149		
Total unadjusted, mean (SD)	4.9 (4.2)	5.0 (4.5)		
Adjusted, mean (95% CI)				
Baseline and multiple respondents	5.0 (4.4 to 5.6)	5.0 (4.3 to 5.6)	0 (−0.9 to 0.9)	.93
Baseline, multiple respondents, and study site	5.0 (4.4 to 5.6)	5.0 (4.3 to 5.7)	0 (−0.9 to 0.9)	.96
Baseline, multiple respondents, study site, race, sex, and primary or additional surrogate	4.6 (3.9 to 5.3)	4.6 (3.8 to 5.4)	0 (−0.9 to 0.9)	.97
Consistent with depression (score 8), adjusted for baseline and multiple respondents, % (95% CI)	24 (17 to 31)	22 (16 to 30)	1.09 (0.62 to 1.92)c	.77
Impact of Events Scale-Revised (IES-R) Score at 3 mo[d]				
No. of surrogate decision makers	161	145		
Total unadjusted, mean (SD)	25.6 (18.0)	20.7 (18.3)		
Adjusted, mean (95% CI)				
Multiple respondents	25.9 (22.8 to 29.0)	21.3 (18.0 to 24.6)	4.60 (0.01 to 9.10)	.0495
Multiple respondents and study site	25.5 (22.7 to 29.0)	21.3 (17.9 to 24.7)	4.5 (0 to 9.0)	.05
Multiple respondents, study site, race, sex,	24.2 (20.6 to 27.8)	19.9 (16.1 to 23.7)	4.3 (−0.2 to 8.9)	.06

	Surrogate Decision Makers		Difference Between Groups, Mean (95% CI)	P Value
	Intervention Group	Control Group		
and primary or additional surrogate				
Multiple respondents, study site, race, sex, primary or additional surrogate, and patient death by time of interview	25.3 (21.7 to 28.9)	21.3 (17.5 to 25.1)	4.1 (−0.3 to 8.5)	.06
Consistent with PTSD (score >33), adjusted for multiple respondents, % (95% CI)	34 (27 to 42)	25 (18 to 33)	1.56 (0.90 to 2.60)c	.10
IES-R Avoidance Subscale Score at 3 mo[e]				
No. of surrogate decision makers	161	145		
Total unadjusted, mean (SD)	8.8 (7.1)	7.1 (6.9)		
Adjusted, mean (95% CI)				
Multiple respondents	8.8 (7.7 to 10.0)	7.1 (5.9 to 8.4)	1.70 (0.02 to 3.30)	.048
Multiple respondents and study site	8.8 (7.7 to 9.9)	7.1 (5.9 to 8.3)	1.6 (0 to 3.3)	.06
Multiple respondents, study site, race, sex, and primary or additional surrogate	8.5 (7.2 to 9.8)	6.9 (5.6 to 8.2)	1.5 (−0.1 to 3.2)	.07
IES-R Hyperarousal Subscale Score at 3 mo[e]				
No. of surrogate decision makers	161	145		
Total unadjusted, mean (SD)	5.9 (5.3)	4.3 (5.0)		
Adjusted, mean (95% CI)				
Multiple respondents	5.9 (5.0 to 6.8)	4.4 (3.4 to 5.4)	1.5 (0.1 to 2.8)	.03
Multiple respondents and study site	5.8 (5.0 to 6.8)	4.4 (3.4 to 5.4)	1.5 (0.1 to 2.8)	.03
Multiple respondents, study site, race, sex, and primary or additional surrogate	5.4 (4.4 to 6.4)	4.0 (2.9 to 5.1)	1.4 (0.1 to 2.8)	.04
IES-R Intrusion Subscale Score at 3 mo[f]				
No. of surrogate decision makers	161	145		
Total unadjusted, mean (SD)	11.0 (7.9)	9.4 (8.2)		
Adjusted, mean (95% CI)				
Multiple respondents	11.1 (9.7 to 12.4)	9.7 (8.2 to 11.1)	1.4 (−0.6 to 3.4)	.17
Multiple respondents and study site	11.1 (9.8 to 12.4)	9.7 (8.3 to 11.1)	1.4 (−0.6 to 3.4)	.17
Multiple respondents, study site, race, sex, and primary or additional surrogate	10.0 (8.4 to 11.6)	8.8 (7.2 to 10.4)	1.3 (−0.7 to 3.3)	.21

Abbreviation: PTSD, posttraumatic stress disorder.

[a] This is the primary outcome for the study. The range is 0 (best) to 42 (worst) with a minimal clinically important difference of 1.5.

[b] The range is 0 (best) to 21 (worst).

[c] Indicates an odds ratio instead of a mean.

[d] The range is 0 (best) to 88 (worst).

[e] The range is 0 (best) to 32 (worst).

[f] The range is 0 (best) to 24 (worst).

Table 4

Support for and Satisfaction of Surrogate Decision Makers

	Intervention Group	Control Group	Odds Ratio (95% CI)	P Value
After-Death Bereaved Family Interview				
Encourage Advance Care Planning Dimension				
Answered "yes" to all 3 patient preference measures, % (95% CI)[a]	75 (67 to 82)	83 (75 to 89)	0.63 (0.34 to 1.16)	.14
Answered "yes" to "Did physician discuss patient wishes about medical treatment?," No. (%)	144 (95)	131 (94)		
Answered "yes" to "Did physician discuss if care was consistent with patient wishes?," No. (%)	136 (90)	133 (96)		
Answered "yes" to "Were all medical procedures and treatments consistent with patient wishes?," No. (%)	135 (89)	128 (92)		
Dimension Score, mean (95% CI)[a,b]			**Difference Between Groups (95% CI)**	
Physical comfort and emotional support	0.14 (0.10 to 0.18)	0.11 (0.07 to 0.15)	0.02 (−0.02 to 0.07)	.32
Inform and promote shared decision making	0.18 (0.14 to 0.22)	0.15 (0.11 to 0.19)	0.04 (−0.02 to 0.09)	.22
Encourage advance care planning	0.16 (0.10 to 0.22)	0.13 (0.07 to 0.19)	0.04 (−0.04 to 0.10)	.39
Focus on individual	0.20 (0.16 to 0.24)	0.16 (0.12 to 0.20)	0.04 (−0.02 to 0.10)	.21
Attend to emotional and spiritual needs of the family	0.14 (0.10 to 0.18)	0.11 (0.07 to 0.15)	0.02 (−0.02 to 0.07)	.32
Overall[c]	8.80 (8.54 to 9.06)	8.99 (8.71 to 9.27)	−0.19 (−0.57 to 0.19)	.33
24-item Family Satisfaction in the Intensive Care Unit Survey Score, mean (95% CI)[a,d]				
Satisfaction with care subscale	81.2 (78.2 to 84.2)	84.0 (80.8 to 87.2)	−2.8 (−7.1 to 1.4)	.19
Satisfaction with decision-making subscale	80.9 (77.9 to 83.9)	84.6 (81.2 to 88.0)	−3.6 (−8.1 to 0.9)	.11
Total score	81.1 (78.3 to 83.9)	84.3 (81.3 to 87.3)	−3.1 (−7.3 to 1.0)	.13

[a] Adjusted for multiple respondents and study site.

[b] Calculated as the sum of negative responses to individual items within each domain divided by the number of items in the domain (ie, problem score). A higher problem score is an indication of more opportunities to improve care or more concerns with quality of care.

[c] Indicates a summary for items reflecting patient-focused and family-centered care (range, 0 [worst] to 10 [best]).

[d] The range is 0 (worst) to 100 (best).

Table 5

Patient Outcomes

Outcome	Median (Interquartile Range)		Difference BetweenGroups (95% CI)	P Value
	Intervention Group (n = 130)	Control Group (n = 126)		
Total ventilator days	19 (15 to 31)	21 (14 to 35)	−2 (−4 to 2)	.59
After randomization	10 (5 to 20)	12 (5 to 27)	−2 (−3 to 1)	.42
Total ICU days	19 (15 to 26)	20 (15 to 30)	−1 (−3 to 1)	.51
After randomization	9 (6 to 15)	10 (5 to 17)	−1 (−2 to 1)	.72
Total hospital days	35 (23 to 52)	36 (23 to 54)	−1 (−6 to 4)	.78
For deceased patients[a]	25 (18 to 36)	24 (14 to 39)	1 (−7 to 4)	.60
After randomization	19 (12 to 37)	23 (12 to 39)	−4 (−6 to 3)	.51
	No. (%)		Odds Ratio (95% CI)	
Hospital mortality	49 (38)	51 (40)	0.89 (0.53 to 1.47)	.65
Limitations of ICU treatment				
Mechanical ventilation	40 (31)	33 (26)	1.3 (0.7 to 2.2)	.41
Dialysis	13 (10)	15 (12)	0.8 (0.4 to 1.8)	.64
Nutrition	18 (14)	21 (17)	0.8 (0.4 to 1.6)	.60
Vasopressors	18 (14)	19 (15)	0.9 (0.4 to 1.8)	.86
Hospital discharge disposition[b]				
Home	15 (19)	18 (24)		
Home with paid assistance	10 (12)	7 (9)		
Hospice	3 (4)	4 (5)		
Acute rehabilitation facility	22 (27)	15 (20)		.62
Long-term acute care hospital	12 (15)	12 (16)		
Other acute care facility	0	1 (1)		
Skilled nursing facility	19 (23)	16 (21)		
Other	0	2 (3)		

Abbreviation: ICU, intensive care unit.

[a]There were 49 patients who died in the intervention group and 51 in the control group.

[b]There were 81 patients discharged from the hospital in the intervention group and 75 in the control group.