ORIGINAL ARTICLE

A Randomized Trial of a Family-Support Intervention in Intensive Care Units

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ABSTRACT

BACKGROUND

Surrogate decision makers for incapacitated, critically ill patients often struggle with decisions related to goals of care. Such decisions cause psychological distress in surrogates and may lead to treatment that does not align with patients' preferences.

METHODS

We conducted a stepped-wedge, cluster-randomized trial involving patients with a high risk of death and their surrogates in five intensive care units (ICUs) to compare a multicomponent family-support intervention delivered by the interprofessional ICU team with usual care. The primary outcome was the surrogates' mean score on the Hospital Anxiety and Depression Scale (HADS) at 6 months (scores range from 0 to 42, with higher scores indicating worse symptoms). Prespecified secondary outcomes were the surrogates' mean scores on the Impact of Event Scale (IES; scores range from 0 to 88, with higher scores indicating worse symptoms), the Quality of Communication (QOC) scale (scores range from 0 to 100, with higher scores indicating better clinician–family communication), and a modified Patient Perception of Patient Centeredness (PPPC) scale (scores range from 1 to 4, with lower scores indicating more patient- and family-centered care), as well as the mean length of ICU stay.

RESULTS

A total of 1420 patients were enrolled in the trial. There was no significant difference between the intervention group and the control group in the surrogates' mean HADS score at 6 months (11.7 and 12.0, respectively; beta coefficient, −0.34; 95% confidence interval [CI], −1.67 to 0.99; P=0.61) or mean IES score (21.2 and 20.3; beta coefficient, 0.90; 95% CI, −1.66 to 3.47; P=0.49). The surrogates' mean QOC score was better in the intervention group than in the control group (69.1 vs. 62.7; beta coefficient, 6.39; 95% CI, 2.57 to 10.20; P=0.001), as was the mean modified PPPC score (1.7 vs. 1.8; beta coefficient, −0.15; 95% CI, −0.26 to −0.04; P=0.006). The mean length of stay in the ICU was shorter in the intervention group than in the control group (6.7 days vs. 7.4 days; incidence rate ratio, 0.90; 95% CI, 0.81 to 1.00; P=0.045), a finding mediated by the shortened mean length of stay in the ICU among patients who died (4.4 days vs. 6.8 days; incidence rate ratio, 0.64; 95% CI, 0.52 to 0.78; P<0.001).

CONCLUSIONS

Among critically ill patients and their surrogates, a family-support intervention delivered by the interprofessional ICU team did not significantly affect the surrogates' burden of psychological symptoms, but the surrogates' ratings of the quality of communication and the patient- and family-centeredness of care were better and the length of stay in the ICU was shorter with the intervention than with usual care. (Funded by the UPMC Health System and the Greenwall Foundation; PARTNER ClinicalTrials.gov number, NCT01844492.)

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This article was published on May 23, 2018, at NEJM.org.

DOI: 10.1056/NEJMoa1802637

Approximately one in five persons in the United States dies in or shortly after discharge from an intensive care unit (ICU),[1] typically after a decision has been made by the patient's surrogate decision maker to forgo life-prolonging therapies.[2-4] Problems with communication between clinicians and surrogates in ICUs have been well documented; these include a failure to conduct timely interdisciplinary meetings with the family,[5-7] missed opportunities to provide emotional support to surrogates,[8,9] and inadequate discussion of prognosis,[10,11] patients' values,[12-14] and the option of comfort-focused treatment.[15] These breakdowns in communication may contribute to the use of expensive, burdensome treatments that do not align with patients' values and preferences[16-18] and to long-term symptoms of psychological distress among surrogates.[19,20]

Although guidelines from professional societies recommend strategies for supporting the families of critically ill patients,[21-23] evidence suggests that many families who might benefit from such support do not receive it.[7] We therefore developed an intervention, to be delivered by the existing interprofessional ICU team, that is grounded in modern decision theory, to address both the affective and the cognitive challenges that are encountered by surrogate decision makers.[24-26] We hypothesized that the intervention would lessen surrogates' long-term burden of psychological symptoms, improve the quality of decision making and clinician–family communication, and shorten the duration of intensive treatment among patients who ultimately do not survive.

Methods

Trial Design and Oversight

We conducted the multicenter, stepped-wedge, cluster-randomized PARTNER (Pairing Re-engineered ICU Teams with Nurse-Driven Emotional Support and Relationship-Building) trial to compare a multicomponent family-support intervention delivered by the interprofessional ICU team (intervention) with usual care (control). According to the stepped-wedge, cluster-randomized trial design, each ICU (cluster) began in the control phase and transitioned to the intervention phase at a randomly assigned time (wedge). We selected cluster randomization rather than randomization of individual patients because the intervention involves groups of clinicians and affects ICU-level care processes; therefore, randomization of individual patients within an ICU would introduce the risk that intervention-based practices would be used in the control group.[27,28]

The institutional review board of the University of Pittsburgh, the quality-improvement committee of the UPMC Health System, and the leadership of participating ICUs approved the project. The delivery of the intervention was judged to be a quality-improvement project because its primary purpose was to increase the implementation of behaviors that are recommended in practice statements from professional societies (e.g., provision of emotional support and timely conduct of interdisciplinary meetings with the family).[21-23] The surrogates of eligible patients were informed of the quality-improvement project by clinical staff. The long-term follow-up of surrogates was judged to be research. Therefore, surrogates provided written informed consent for their participation. Because of an administrative error by the research team regarding whether quality-improvement projects could be registered on ClinicalTrials.gov, trial registration was finalized after enrollment commenced. The trial protocol is available with the full text of this article at NEJM.org.

Trial Centers and Participants

We conducted the trial in five ICUs at five hospitals in the UPMC Health System. The ICUs were selected to provide diversity with respect to hospital setting, patient demographic characteristics, and physician staffing models. The trial involved two specialized ICUs (one specializing in neurologic illnesses and one in transplantation surgery) at academic hospitals, in which intensivist physicians provided care for all patients in collaboration with a primary attending physician, as well as two medical–surgical ICUs and one medical ICU at community hospitals, in which intensivist physicians served as the attending physician of record for all patients. Each of the five ICUs had separate leadership, physicians, and nurses but used the same system for electronic medical records (Cerner).

The trial included all patients in the five ICUs who met the eligibility criteria during the enrollment period. Inclusion criteria were an age of 18 years or older, a lack of decision-making capacity as judged by the patient's attending physician, and at least one of the following clinical charac-

teristics: receipt of mechanical ventilation for at least 4 consecutive days, an estimated chance of death during hospitalization of at least 40% as judged by the patient's attending physician, or an estimated chance of severe long-term functional impairment of at least 40% as judged by the patient's attending physician. We excluded patients who did not have a surrogate decision maker or were receiving only comfort-focused treatment at the time that they were eligible for enrollment. For each patient, we enrolled one surrogate decision maker whom the family identified as the patient's main surrogate. We excluded surrogates who were younger than 18 years old or were unable to read or understand English.

RANDOMIZATION AND TREATMENT GROUPS

After a baseline period of data collection, we used a computer-generated randomization scheme to determine the order in which each ICU would cross over from the control phase to the intervention phase, with a new crossover occurring every 6 months. This trial design allowed us to stagger the implementation of the intervention while maintaining concurrent control over data collection in the ICUs that were not yet using the intervention. Patient enrollment began in July 2012 and ended in August 2015. Long-term follow-up of surrogates was completed in February 2016.

A detailed description of the intervention is provided in the protocol. The intervention is grounded in the theory of cognitive–emotional decision making, which suggests that medical decisions are influenced by both the affective and the cognitive challenges of making consequential health decisions.[25] Therefore, the intervention entailed guideline-recommended strategies for providing emotional support to surrogates and for ensuring frequent clinician–family communication.[21-23] The intervention was delivered by members of the interprofessional ICU team and was overseen by four to six nurses in each ICU (called the PARTNER nurses), who were nominated by the ICU director because they were thought to possess strong communication skills.

The intervention involved three components. First, the PARTNER nurses received advanced communication training that focused on skills for supporting families of seriously ill patients. The 12-hour training included didactic teaching, modeling of the communication skills, practice of the skills with trained medical actors, and provision of structured feedback. Second, a family-support pathway was instituted, in which the PARTNER nurses met with families on a daily basis, according to a standardized protocol, and arranged clinician–family meetings within 48 hours after enrollment and every 5 to 7 days thereafter (Fig. 1). Third, intensive support for implementation was provided to each ICU by a quality-improvement specialist, to incorporate the family-support pathway into clinicians' workflow.

Patients in the control group received usual care. At the time of the trial, none of the ICUs had a protocolized approach to communication with families or required family meetings to be conducted at set intervals.

DATA COLLECTION

Research staff, who were unaware of the participants' treatment-group assignments, conducted telephone interviews with surrogate decision makers 6 months after the patient's hospital discharge. During the interviews, they obtained the surrogate's demographic information and responses to surveys. Following methods that had been described previously,[29] we used the electronic medical record to determine the patient's demographic characteristics, primary diagnosis, source of admission to the ICU, severity of acute illness on admission to the ICU as determined with the modified Simplified Acute Physiology Score (SAPS) III,[30] number of coexisting conditions as determined with the Elixhauser Comorbidity Index score,[31] and disposition on hospital discharge. At the 6-month follow-up of surrogates, we assessed the patient's vital status and used the Katz Index of Independence in Activities of Daily Living (scores range from 0 to 6, with lower scores indicating more independence) to assess functional status in patients who had not died.[32] We used the Social Security Death Master File to determine the vital status at 6 months for patients whose surrogate was lost to follow-up. We calculated the cost per patient to use the intervention by summing the overall cost of the intervention and dividing it by the number of patients in the intervention group (for details, see Table S1 in the Supplementary Appendix, available at NEJM.org).

OUTCOMES

We measured the effect of the intervention with respect to three outcome domains: surrogates' long-term psychological distress, the quality of

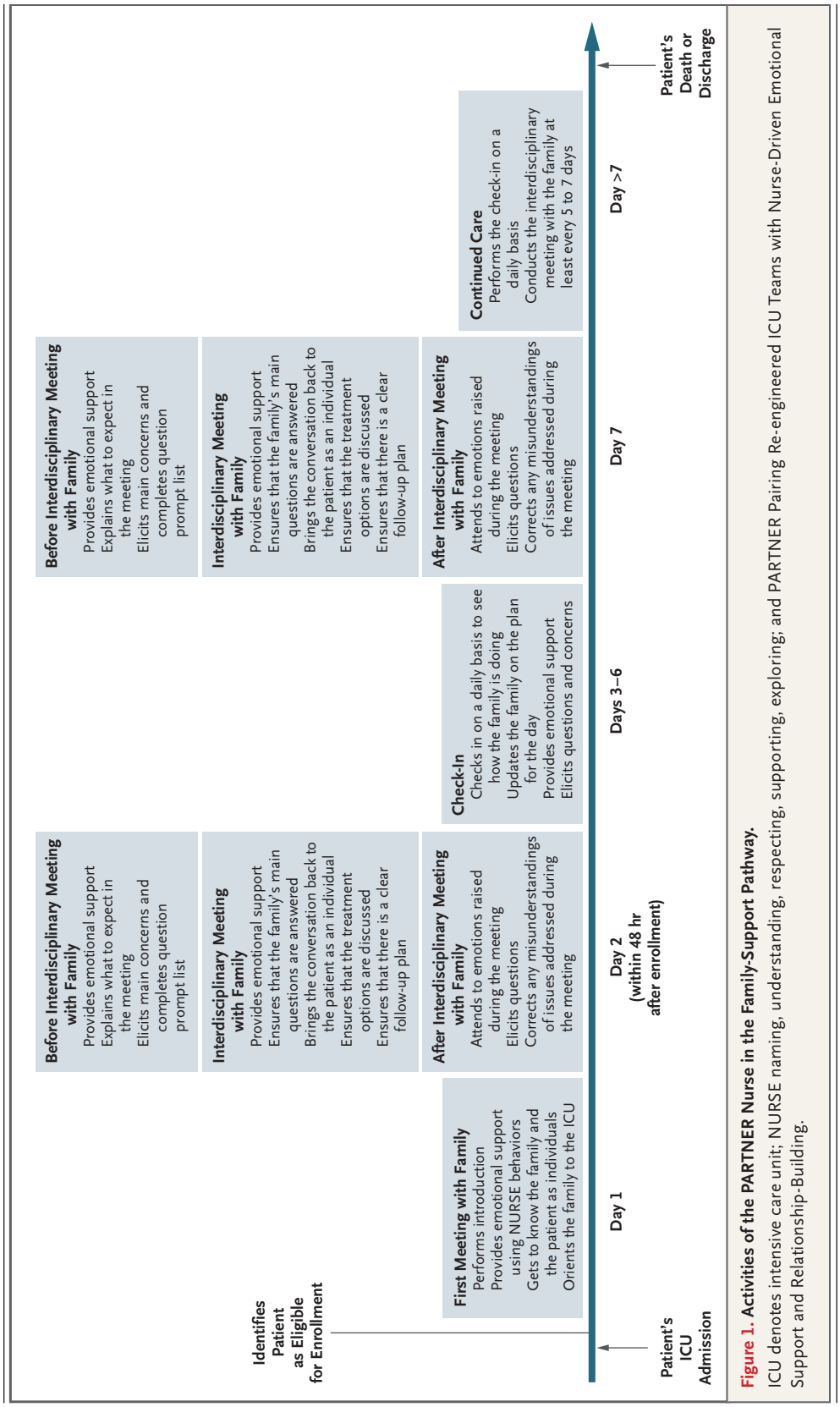

Figure 1. Activities of the PARTNER Nurse in the Family-Support Pathway.

ICU denotes intensive care unit; NURSE naming, understanding, respecting, supporting, exploring; and PARTNER Pairing Re-engineered ICU Teams with Nurse-Driven Emotional Support and Relationship-Building.

decision making and clinician–family communication, and health care utilization. The primary outcome was the surrogates' symptoms of anxiety and depression 6 months after the patient's hospital discharge, as assessed by the mean score on the Hospital Anxiety and Depression Scale (HADS; scores range from 0 to 42, with higher scores indicating worse symptoms).[33] Prespecified secondary outcomes were the surrogates' symptoms of post-traumatic stress disorder, as assessed by the mean score on the Impact of Event Scale (IES; scores range from 0 to 88, with higher scores indicating worse symptoms)[34]; the surrogates' rating of the quality of clinician–family communication, as assessed by the mean score on the Quality of Communication (QOC) scale (scores range from 0 to 100, with higher scores indicating better communication)[35]; the surrogates' rating of the patient- and family-centeredness of care, as assessed by the mean score on the Patient Perception of Patient Centeredness (PPPC) scale (scores range from 1 to 4, with lower scores indicating more patient- and family-centered care)[36] with modifications for use by surrogates; and the mean length of stay in the hospital and in the ICU from the time of trial entry.

STATISTICAL ANALYSIS

The complete statistical analysis plan is provided with the protocol in the Supplementary Appendix. The individual ICU was the unit of randomization, and the individual patient (and corresponding surrogate) was the unit of analysis. We estimated that a sample of 1000 surrogates would provide the trial with 90% power to detect a difference between the intervention group and the control group for the primary outcome that was equivalent to the clinically meaningful difference for the HADS subscales (1.5±4 points),[37] assuming a 25% loss to follow-up at 6 months. This sample would provide the trial with 80% power to detect a small-to-moderate between-group difference for each of the secondary outcomes. All analyses were performed on an intention-to-treat basis. All tests for significance were two-sided. For the primary and secondary outcomes, we used generalized linear mixed models, with ICU and time as random effects, as delineated by Hussey and Hughes.[38,39] We prespecified that all analyses would be adjusted for patient age, modified SAPS III, Elixhauser Comorbidity Index score, use or nonuse of mechanical ventilation, admission source, and baseline patient and surrogate demographic characteristics that were associated with the outcome and had a between-group difference ($P \leq 0.20$) on univariate analysis. For unanswered survey questions, we imputed the value for that question with the patient's mean score for all answered questions on the survey if at least half the questions had been answered.[40] For length-of-stay analyses, we used zero-truncated negative binomial models, with ICU and time as fixed effects.

We conducted several post hoc sensitivity and restricted analyses. First, we assessed for heterogeneity of treatment effect across ICUs in two ways: by checking for interactions between treatment and ICU as a fixed effect, and by refitting the models with stratification according to ICU and comparing the treatment effects across ICUs (horizontal analysis). Second, we assessed for heterogeneity of treatment effect across time in two ways: by checking for interactions between treatment and time point as a fixed effect, and by refitting the models with stratification according to time point and comparing the treatment effects across time points (vertical analysis). We used Gray's semiparametric survival regression model to assess whether the intervention affected the duration of survival during the 6-month follow-up period.[41] We examined the effect of the intervention on the scores on the HADS subscales for anxiety and depression and on the scores on the HADS, IES, QOC scale, and modified PPPC scale when they were analyzed as ordinal or categorical outcomes. To examine whether the effect of the intervention on the surrogate's scores for psychological distress varied according to the patient's outcome, we stratified the analyses according to patients' vital status at hospital discharge.

RESULTS

TRIAL CENTERS AND PARTICIPANTS

The intervention phase was implemented at all five participating ICUs, and they were all included in the intention-to-treat analysis (Fig. S1 in the Supplementary Appendix). During the intervention phase, one ICU was closed by the hospital and another was decreased in size from 28 beds to 20 beds. A total of 1420 patients met the eligibility criteria and were included in the trial (Table 1). Surrogates for 1106 of those patients agreed to be contacted for long-term follow-up, and 809

of those surrogates (73%) completed long-term follow-up (Table 1). There were differences between the treatment groups in some of the patient characteristics at baseline, including an older mean age and higher scores for the severity of acute illness and the number of chronic coexisting conditions in the intervention group than in the control group (Table 1). Demographic characteristics were generally similar between patients whose surrogates completed long-term follow-up and patients whose surrogates did not (Table S2 in the Supplementary Appendix).

PRIMARY AND SECONDARY OUTCOMES

Results for the primary and secondary outcomes are summarized in Table 2. After adjustment for differences in baseline characteristics, there was no significant difference between the intervention group and the control group in the primary outcome, which was the surrogates' mean HADS score at 6 months (11.7 and 12.0, respectively; beta coefficient for estimated effect of intervention, −0.34; 95% confidence interval [CI], −1.67 to 0.99; P=0.61). There was also no significant difference between the intervention group and the control group in the surrogates' symptoms of post-traumatic stress disorder at 6 months, as assessed by the mean IES score (21.2 and 20.3, respectively; beta coefficient, 0.90; 95% CI, −1.66 to 3.47; P=0.49).

The surrogates' rating of the quality of clinician–family communication during hospitalization was significantly better in the intervention group than in the control group (mean QOC score, 69.1 vs. 62.7; beta coefficient, 6.39; 95% CI, 2.57 to 10.20; P=0.001), as was the surrogates' rating of the patient- and family-centeredness of care (mean modified PPPC score, 1.7 vs. 1.8; beta coefficient, −0.15; 95% CI, −0.26 to −0.04; P=0.006). The mean length of stay in the ICU was significantly shorter in the intervention group than in the control group (6.7 days vs. 7.4 days; incidence rate ratio, 0.90; 95% CI, 0.81 to 1.00; P=0.045), as was the mean length of stay in the hospital where the ICU was located (10.4 days vs. 13.5 days; incidence rate ratio, 0.77; 95% CI, 0.69 to 0.87; P<0.001) (Table 2). The effect of the intervention on length of stay was mediated by the shortened mean length of stay in the ICU among patients who died (4.4 days in the intervention group vs. 6.8 days in the control group; incidence rate ratio, 0.64; 95% CI, 0.52 to 0.78; P<0.001). The intervention did not significantly affect the mean length of stay in the ICU among patients who survived to hospital discharge (8.0 days in the intervention group and 7.6 days in the control group; incidence rate ratio, 1.04; 95% CI, 0.93 to 1.18; P=0.48).

CLINICAL AND EXPLORATORY OUTCOMES

In-hospital mortality was higher in the intervention group than in the control group (36.0% vs. 28.5%; odds ratio, 1.43; 95% CI, 1.10 to 1.87; P=0.008), but mortality at 6 months did not differ significantly between the two groups (60.4% and 55.4%, respectively; adjusted odds ratio, 1.18; 95% CI, 0.93 to 1.50; P=0.17) (Table 3). There was no significant difference between the intervention group and the control group in the mean score on the Katz Index of Independence in Activities of Daily Living at 6 months (4.4 and 4.0, respectively; beta coefficient, −0.16 to 1.01; P=0.16), the percentage of patients who were living independently at home at 6 months (0.8% and 0.7%; odds ratio, 1.15; 95% CI, 0.13 to 9.89; P=0.90), or the percentage of patients who were able to live at home at any point during the 6-month follow-up period (5.6% and 7.5%; odds ratio, 0.69; 95% CI, 0.38 to 1.27; P=0.23). The mean cost to use the intervention was $170 per patient (Table S1 in the Supplementary Appendix).

Exploratory sensitivity analyses revealed that the effect of the intervention was consistent over time during the trial period and was generally consistent across ICUs. In an analysis performed with Gray's semiparametric survival regression model, the intervention did not have a significant effect on the duration of survival during the 6-month period of combined inpatient and outpatient follow-up. There was no significant difference between the two groups in analyses of the HADS and IES scores as categorical outcomes with established cutoff points or in analyses of the scores on the HADS subscales of anxiety and depression as continuous, dichotomous, and ordinal outcomes. In an analysis of the QOC score as a dichotomous outcome (high [≥80] vs. low [<80]), the proportion of surrogates with a high QOC score was larger in the intervention group than in the control group. In an analysis of the modified PPPC score as an ordinal outcome with three categories, the percentage of surrogates with a score in the highest patient-centeredness category was higher in the intervention group than

Table 1. Characteristics of the Patients and Surrogates at Baseline.*

Characteristic	Intervention	Control	P Value†
Patients			
Total no.	547	873	
Age — yr	67.5±14.9	63.3±15.5	<0.001
Female sex — no. (%)	290 (53.0)	405 (46.4)	0.02
Primary diagnosis — no. (%)‡			<0.01
Cardiovascular cause	33 (6.0)	36 (4.1)	
Pulmonary cause	107 (19.6)	138 (15.9)	
Gastrointestinal cause	49 (9.0)	94 (10.8)	
Toxicologic cause	18 (3.3)	38 (4.4)	
Infection or sepsis	159 (29.1)	212 (24.4)	
Neurologic cause	106 (19.4)	173 (19.9)	
Oncologic cause	18 (3.3)	59 (6.8)	
Other	56 (10.3)	118 (13.6)	
Source of admission to the ICU — no. (%)			<0.001
Direct admission	50 (9.1)	224 (25.7)	
Transfer from emergency department	422 (77.2)	549 (62.9)	
Transfer from other hospital	73 (13.4)	100 (11.5)	
Transfer from skilled nursing facility	2 (0.4)	0	
Modified SAPS III§	51.0±11.8	49.4±12.0	0.02
Elixhauser Comorbidity Index score¶	5.8±2.4	5.1±2.5	<0.001
Use of mechanical ventilation during hospitalization — no. (%)	479 (87.6)	759 (86.9)	0.73
Surrogates			
Total no.	429	677	
Age — yr	57.1±13.7	56.4±13.6	0.46
Female sex — no. (%)	284 (66.2)	480 (70.9)	0.06
Relationship to patient — no. (%)			0.04
Spouse or partner	161 (37.5)	295 (43.6)	
Parent	28 (6.5)	63 (9.3)	
Child	163 (38.0)	197 (29.1)	
Sibling	53 (12.4)	81 (12.0)	
Other	24 (5.6)	41 (6.1)	

* Plus–minus values are means ±SD. Percentages may not sum to 100 because of rounding. ICU denotes intensive care unit. For details, see Table S2 in the Supplementary Appendix.
† P values were calculated with Student's t-test or Pearson's chi-square test.
‡ Data were missing for one patient in the intervention group and five patients in the control group.
§ The modified Simplified Acute Physiology Score (SAPS) III ranges from 0 to 166, with higher scores indicating a greater severity of acute illness.
¶ The Elixhauser Comorbidity Index score ranges from 0 to 29, with higher scores indicating a higher number of chronic coexisting conditions.

in the control group (79.2% vs. 63.8%; odds ratio, 2.03; 95% CI, 1.41 to 2.93; P<0.001). For further results of exploratory analyses, see the Supplementary Appendix.

DISCUSSION

In the multicenter PARTNER trial, we found that, among critically ill patients and their surrogates,

Table 2. Primary and Secondary Outcomes.*

Outcome	Unadjusted Analysis		Adjusted Analysis†			
	Intervention	Control	Intervention	Control	Estimated Effect of Intervention (95% CI)	P Value
			mean (95% CI)			
Surrogates' burden of psychological symptoms						
No. of surrogates assessed	308	501				
HADS score‡	11.7±7.9	12.1±8.5	11.7 (10.7 to 12.7)	12.0 (11.3 to 12.8)	–0.34 (–1.67 to 0.99)§	0.61
IES score¶	20.5±18.1	20.7±17.7	21.2 (19.3 to 23.2)	20.3 (18.8 to 21.9)	0.90 (–1.66 to 3.47)§	0.49
Quality of decision making and communication						
No. of surrogates assessed	308	501				
QOC score‖	69.7±23.5	63.0±24.8	69.1 (66.2 to 72.0)	62.7 (60.4 to 65.0)	6.39 (2.57 to 10.20)§	0.001
Modified PPPC score**	1.6±0.6	1.8±0.7	1.7 (1.6 to 1.7)	1.8 (1.8 to 1.9)	–0.15 (–0.26 to –0.04)§	0.006
Health care utilization						
No. of patients assessed	547	873				
Length of ICU stay — days	8.1±8.6	8.8±8.8	6.7 (6.1 to 7.2)	7.4 (7.0 to 7.9)	0.90 (0.81 to 1.00)††	0.045
Length of hospital stay — days	11.8±13.1	15.5±19.2	10.4 (9.5 to 11.3)	13.5 (12.6 to 14.4)	0.77 (0.69 to 0.87)††	<0.001

* Plus–minus values are means ±SD.
† Adjusted analyses were performed with regression models. All models were adjusted for patient's age, modified SAPS III, Elixhauser Comorbidity Index score, use or nonuse of mechanical ventilation, primary diagnosis, and admission source.
‡ Scores on the Hospital Anxiety and Depression Scale (HADS) range from 0 to 42, with higher scores indicating worse symptoms. The adjusted analysis included the following additional covariates: patient's vital status at 6 months after discharge, the surrogate's sex, and the surrogate's relationship to the patient.
§ The result is a beta coefficient calculated with generalized linear mixed modeling.
¶ Scores on the Impact of Event Scale (IES) range from 0 to 88, with higher scores indicating worse symptoms. The adjusted analysis included the following additional covariates: patient's vital status at 6 months after discharge, the surrogate's sex, and the surrogate's relationship to the patient.
‖ Scores on the Quality of Communication (QOC) scale range from 0 to 100, with higher scores indicating better communication. The adjusted analysis included the following additional covariate: patient's race (black vs. nonblack).
** Scores on the modified Patient Perception of Patient Centeredness (PPPC) scale range from 1 to 4, with lower scores indicating more patient- and family-centered care. The adjusted analysis included the following additional covariates: surrogate's age and sex.
†† The result is an incidence rate ratio calculated with zero-truncated negative binomial regression modeling.

a low-cost intervention delivered by the interprofessional ICU team did not significantly affect the surrogates' burden of psychological symptoms at 6 months, but the surrogates' ratings of the quality of communication and the patient- and family-centeredness of care were better and the length of stay in the ICU was shorter with the intervention than with usual care. We propose three possible explanations for why the intervention did not affect the surrogates' long-term burden of psychological symptoms. First, the intervention was delivered only during each patient's stay in the ICU and therefore did not address events that occurred after discharge from the ICU that may have contributed to psychological distress, such as bereavement, financial strain, and the demands of caregiving.[42] Our findings are consistent with the results of two other recent trials, which showed that communication interventions that were delivered during the ICU stay did not improve most outcomes related to surrogates' long-term psychological distress.[43,44] Sec-

Table 3. Patients' Clinical Outcomes.

Outcome	Unadjusted Analysis		Adjusted Analysis*			
	Intervention (N=547)	Control (N=873)	Intervention (N=547)	Control (N=873)	Odds Ratio (95% CI)	P Value
	no. of patients (%)		*% (95% CI)*			
In-hospital death	208 (38.0)	264 (30.2)	36.0 (26.2 to 45.7)	28.5 (20.1 to 36.9)	1.43 (1.10 to 1.87)	0.008
Death at 6 mo	339 (62.0)	472 (54.1)	60.4 (56.0 to 64.9)	55.4 (51.9 to 59.0)	1.18 (0.93 to 1.50)	0.17
Living independently at home at 6 mo	3 (1.0)	13 (2.6)	0.8 (–0.5 to 2.2)	0.7 (–0.2 to 1.6)	1.15 (0.13 to 9.89)	0.90

* Adjusted analyses were performed with regression models. All models were adjusted for patient's age, modified SAPS III, Elixhauser Comorbidity Index score, use or nonuse of mechanical ventilation, primary diagnosis, and admission source. These analyses included the following additional covariate: patient's sex. Odds ratios were calculated with logistic-regression modeling.

ond, it is possible that the target of the intervention — the stress of making decisions for others — may contribute less than has been previously thought to surrogates' long-term psychological distress.[20] Third, the levels of psychological distress in our cohort were significantly lower than levels that have been observed previously, making it difficult to further reduce the burden of symptoms.[45]

Numerous previous interventions to improve decision making for patients with serious illness were largely unsuccessful; these included providing model-derived prognostic estimates and information about patients' treatment preferences to physicians,[46] conducting structured clinician–family meetings,[47] and having palliative care physicians convey the prognosis.[43] Preliminary evidence from a recent trial of a communication-facilitator intervention in ICUs suggests that intensive psychosocial support for families may decrease the duration of intensive treatment before the patient's death without increasing psychological distress among surrogates.[44] However, the communication-facilitator intervention was delivered by external interventionists. The results of our trial suggest that it is feasible to train members of the existing interprofessional ICU team to deliver a family-support intervention. Future research might further our understanding of the comparative effectiveness and scalability of these different approaches to family support in ICUs.

Although we observed higher in-hospital mortality in the intervention group than in the control group, we did not find a significant difference between the two groups in 6-month mortality or in the percentage of patients who were living independently at home at 6 months, which was less than 3% in each group. The intervention resulted in significant improvements in markers of the quality of decision making, including the patient- and family-centeredness of care and the quality of clinician–family communication. Taken together, these findings suggest that the intervention allowed surrogates to transition a patient's treatment to comfort-focused care when doing so aligned with the patient's values. A previous study that was conducted in the context of advanced illness suggested that treatment that accords with the patient's preferences may lead to shorter survival among those who prioritize comfort over longevity.[48]

Our trial has several strengths. First, the intervention that we tested is grounded in theory, has a low cost, and aligns with national recommendations to leverage the interprofessional clinical team to better support patients with advanced illness and their families.[49] Second, we incorporated strategies from the field of implementation science to develop an intervention that can be disseminated in hospitals that are able to deploy quality-improvement projects.[50] Third, we assessed the effect of the intervention from the multiple perspectives that patients, health care providers, policy makers, and health systems will need to comprehensively appraise the intervention; these include surrogates' psychological outcomes, patients' outcomes, the quality of communication and decision making, and health care utilization.

This trial also has several limitations. Although we recruited a large cohort from a diverse group

of ICUs, our sample was limited to one region of the country. Second, despite randomization, there were imbalances between treatment groups in baseline characteristics, which most likely arose from differences in patient demographics among the relatively small number of participating ICUs. Although we used appropriate statistical techniques to adjust for these differences, we cannot rule out the possibility that residual confounding influenced the findings. It is reassuring, however, that our findings were robust in numerous sensitivity analyses. Third, because the trial used automated strategies to abstract data from electronic medical records, we were not able to quantitatively ascertain the ways in which the intervention changed care processes surrounding family communication. However, we conducted weekly site visits that involved direct observation of the PARTNER nurses delivering the intervention, which qualitatively revealed high levels of adherence to the protocolized family-support pathway. Fourth, results of secondary outcomes were not adjusted for multiple comparisons, which increases the possibility of type I error. However, we chose a small number of prespecified outcomes, and the positive findings were highly significant.

In conclusion, among critically ill patients and their surrogates, a family-support intervention delivered by the existing interprofessional ICU team did not affect the surrogates' symptoms of depression and anxiety at 6 months, but the surrogates' ratings of the quality of communication and the patient- and family-centeredness of care were better and the length of stay in the ICU was shorter with the intervention than with usual care. Our data are not directive, but they suggest that equipoise is present and that a large replication trial may be conducted in multiple geographic regions to establish the generalizability of the findings in different health systems that have potentially different attitudes and practices regarding care for patients with advanced critical illness.

Supported by an Innovation Award from the UPMC Health System and by the Greenwall Foundation.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We thank the interprofessional ICU teams that participated in the trial for their dedication and effort, Drs. James Tulsky and Anthony Back for their important contributions to the methods that were used to teach communication skills in the intervention, and Dr. Amber Barnato for her thoughtful suggestions on an earlier version of the manuscript.

APPENDIX

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