Published in final edited form as:

Crit Care Med. 2020 February ; 48(2): 176–184. doi:10.1097/CCM.0000000000004113.

Family Care Rituals in the Intensive Care Unit to Reduce Symptoms of Post-Traumatic Stress Disorder in Family Members- A Multicenter, Multinational, Before-and-After Intervention Trial

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Abstract

Objective—To assess the feasibility and efficacy of implementing “Family Care Rituals” as a means of engaging family members in the care of patients admitted to the ICU with a high risk of ICU mortality on outcomes including stress related symptoms in family members.

Design—Prospective, before-and-after intervention evaluation

Setting—2 United States academic medical ICU’s, and 1 Italian academic medical/surgical ICU

Participants—Family members of patients who had an attending predicted ICU mortality of greater than 30% within the first 24 hours of admission.

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The remaining authors have disclosed that they do not have any potential conflicts of interest.

Intervention—A novel intervention titled “Family Care Rituals” (FCR) during which, following a baseline observation period, family members enrolled in the intervention phase were given an informational booklet outlining opportunities for engagement in care of the patient during their ICU stay.

Measurements and Main Results—Primary outcome was symptoms of Post-Traumatic Stress Disorder (PTSD) in family members 90 days after patient death or ICU discharge. Secondary outcomes included symptoms of depression, anxiety, and family satisfaction. At 90 day follow-up, 131 of 226 family members (58.0%) responded pre-intervention and 129 of 226 family members (57.1%) responded post-intervention. Symptoms of PTSD were significantly higher pre-intervention than post-intervention (39.2% vs 27.1%, unadjusted OR 0.58, $p=0.046$). There was no significant difference in symptoms of depression (26.5% vs 25.2%, unadjusted OR 0.93, $p=0.818$), anxiety (41.0% vs 45.5%, unadjusted OR 1.20, $p=0.234$), or mean satisfaction scores (85.1 vs 89.0, unadjusted OR 3.85, $p=0.052$) pre- vs post-intervention 90 days after patient death or ICU discharge.

Conclusions—Offering opportunities such as FCR for family members to be involved with providing care for family members in the ICU was associated with reduced symptoms of PTSD. This intervention may lessen the burden of stress related symptoms in family members of ICU patients.

Keywords

Critical Care; Stress Disorders, Post-Traumatic; Family; Bereavement

INTRODUCTION

Symptoms of stress, anxiety or depression, and post-traumatic stress disorder (PTSD) among family members of intensive care unit (ICU) patients are common and have been collectively identified as Post-Intensive Care Syndrome-Family (PICS-f) (1). Several deficiencies for providing care in the ICU as perceived by family members have been identified in literature; most commonly related to communication, decision making, sense of control, spirituality, preparation for death, pain, and symptom management (2–9). PICS-f may be related to these shortcomings in care and is likely from multiple factors in the ICU which ultimately strip the family of the ability to provide any direct care or nurturing for their loved one including, but not limited to, variable levels of caregiver training and the chaotic and technical environment in the ICU (10). Many cultures have traditions or rituals around the process of dying that allow families to feel involved and care for their loved ones while they are dying, some of which provided the basis for the intervention tested in this study (11, 12). Moreover, qualitative studies suggest that families want and value a role as a care-provider for their loved ones in the ICU (13–15) and the Society of Critical Care Medicine has released guidelines on family centered care encouraging several domains to improve the families experience of having a loved in the ICU. These include finding ways to encourage family participation in the care of the patient, particularly neonates (16). However, it is unknown what impact this participation will have on PICS-f, and specifically on PTSD, in the adult patient population.

To evaluate the efficacy of engaging family members in the hands-on care of their loved ones at high risk of dying in the ICU, we designed and implemented an intervention named “Family Care Rituals (FCR) in the ICU”. Designed as a prospective, multicenter, multinational before-and-after trial, we hypothesized that offering opportunities for family members to be involved in participating in the care of patients at high risk of dying in the ICU would reduce symptoms of Post-Traumatic Stress Disorder (PTSD) 90 days after death or discharge of the patient from the ICU.

MATERIALS AND METHODS

This was a prospective, multicenter, multinational, before-and-after intervention trial. Family members were eligible if they were visitors for an ICU patient for whom the attending physician predicted ICU mortality higher than 30%. Enrollment for the usual care (before) phase occurred between September of 2015 and September of 2016 and for the intervention (after) phase between February 2016 and March of 2017. Each site had at least a 2-week period after the observation (before) phase completed to allow patients enrolled to be discharged from the ICU prior to initiating the intervention phase. Three academic ICU’s with unrestricted visiting hours (17), participated in this study (Supplementary Table 1 for site enrollment dates and descriptions).

Human subject’s approval was obtained from the institutional review boards of each hospital. All subjects enrolled provided written, informed consent and privacy authorization as directed by the local boards. We obtained a waiver for written documentation of consent for the nurses and physicians involved. The entire study protocol is available at [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02875912) identifier: [NCT02875912](https://clinicaltrials.gov/ct2/show/study/NCT02875912)

Subject selection

Patients were screened within the first 24 hours of admission to the ICU by the research team. For those patients with an attending physician predicted ICU mortality of greater than 30%, the family was approached for enrollment if neither they nor the patient met any exclusion criteria. Exclusion criteria for patients and family were the same and included pregnancy, admission to the ICU for comfort care only (CMO), anticipated ICU length of stay less than 24 hours, age less than 18, and incarceration. Predicted patient ICU mortality of >30%, which was based on the attendings’ clinical experience and has been previously used in the literature (18,19), was selected for family enrollment as the family of patients who were felt to be at an increased likelihood of mortality were hypothesized to benefit most from the intervention, but was not intended as an accurate reflection of actual patient outcome. During enrollment screening, patients with comfort care orders were excluded as we hypothesized that they would be less likely to benefit from this intervention due to an anticipated reduced length of stay in the ICU. Those patients that transitioned to CMO after enrollment were not excluded.

Intervention

Through a multidisciplinary, literature-based, iterative process (see supplemental digital content for full description), seven domains were identified as areas in which family

participation may be of benefit: the 5 physical senses, the personal care of the patient, and the spirituality of the patient and family (Figure 1). These domains were incorporated into an informational booklet that was translated from English into Spanish and Italian. The booklet was intended to act as a framework describing to participating family members examples of ways to engage with the patient at the bedside. Upon enrollment, a researcher delivered the informational booklet, which described the elements of the intervention to be performed by family members, to each enrolled family member. During the delivery of the pamphlet, the researcher would discuss the elements, or rituals, that could be performed by family members outlined in the informational sheet, as suggestions that the family could choose from to perform on their loved one. Each participant was informed that they were under no obligation to perform any of the rituals; specifically, that things that are nursing and hospital duties (providing pillows, cleaning the patient, mouth/ventilator care, for example) would be performed whether or not they participated. After delivery of the pamphlet and discussion with each participating family member, there were no further points of contact between the research team and the participants.

Data Collection

During both phases, survey data was collected from families upon enrollment and at 90 days post-death/discharge of the patient from the ICU via telephone. Nurses were asked to complete surveys daily evaluating what rituals were employed by the family during both phases (Supplementary Figure 1). Given awareness of possible interference of the intervention with nursing workflow, the nurses were asked to complete surveys evaluating their perception of the impact of the intervention on their work flow during the intervention phase (Supplementary Figure 2).

Primary outcome- symptoms of PTSD at 90 days post-death/discharge of patient

Using the Impact of Events Scale-revised (IES-r), families were evaluated via telephone for symptoms of PTSD 90 days after death/discharge of the patient. The IES-r is a validated screen which is widely available online, available in several languages and has been used in ICU populations in several previous studies (20). It is a 22-item questionnaire with each item scored from 0–4, allowing for total scores ranging from 0 to 88. A respondents score of 30 or greater has been previously associated with symptoms of PTSD (21,22), which is distinct from the Diagnostic and Statistical Manual (DSM) of Mental Disorders criteria for the diagnosis of PTSD. The percentage of family members with scores of 30 or greater 90 days after patient death/discharge from the ICU during usual care phase were compared to the intervention phase.

Secondary outcomes

Symptoms of Depression and Anxiety—Symptoms of depression and anxiety were measured at enrollment and at 90 day follow-up using the Hospital Anxiety and Depression Scale (HADS). The HADS is a similarly validated tool previously used in several studies on ICU populations and is a 14-item questionnaire with 7 questions tailored to each depression and anxiety (23,24). We compared the proportion of family members who, at 90 days after patient death/ICU discharge, had a score greater than or equal to 8 in each category (24)

during the 2 study periods. Additionally, we compared the change from the initial (day 0) score to the 90 day score in both phases.

Family Satisfaction in the ICU—Family satisfaction was evaluated at 90 days post-death/discharge of the patient using the Family Satisfaction in the ICU-24 (FS-ICU24) questionnaire, a 24-item questionnaire, which is well validated in ICU populations (25). The mean of these scores during usual care and intervention phases were then compared. Additionally, *a priori*, three questions were selected from the FS-ICU24 that were thought likely to be most impacted by this intervention. The full questions are available in the supplemental digital content, though addressed “satisfied with care”, “included in decision-making”, and “had control over the care.” Mean responses for each were compared between the two phases.

Additional secondary outcomes—We compared the geometric mean patient length-of-stay (LOS) in the ICU, ICU mortality, occurrence of code status change, and incidence of palliative and spiritual care consults. We used the geometric mean LOS instead of an arithmetic mean to account for skewing.

Statistical methods—We based our sample size on prior data (1, 22, 26) which indicate an incidence of symptoms of PTSD in family members of about 33%. To reduce the rate of symptoms of PTSD in the interventional arm to 17%, with an alpha of 0.05 and a power of 0.80, we anticipated needing to enroll 114 subjects in each arm to be able to reject the null hypothesis that there was no difference between the usual care and intervention. In powering for this study, we did not adjust for family clustering per patient. Assuming a lost to follow-up rate at 90 days of 40%, enrolling a total of 450 family members (225 per group) would enable us to identify if families benefited from the intervention.

Where appropriate, results were used to generate unadjusted odds ratios (OR). All outcomes were then adjusted for patient age, gender, if admitting APACHE score was >20, and family gender, level of education, and country of birth, as these have been associated with stress-related symptoms in families (1, 27). Results presented in the text include adjusted outcomes, with unadjusted and adjusted results presented in Table 2. See the supplementary digital content for a full description of the statistical methods used for analysis. All statistical analyses were completed using Stata 14.2, StataCorp LLC, College Station, TX.

RESULTS

We screened 1193 patients during the usual care phase and 1437 during the intervention phase, enrolling family members of 136 patients in the usual care group (11.4% of those screened) and family members of 127 patients in the intervention group (8.8% of those screened). We enrolled 226 family members in each phase with a mean of 1.67 family members per patient in the usual care group and a mean of 1.77 family members per patient in the intervention group (Table 1), and completed follow-up data on 131 in the usual care group and 129 in the intervention group (58.0% and 57.1%, respectively) at 90 days (Figure 2). More than half of enrolled family members were female (66.8% usual care, 65.5%

intervention) and most self-identified as white (usual care 75.2%, intervention 81.4%). Characteristics of both the family members and the patients enrolled are shown in Table 1.

Nurses completed daily observations of bedside rituals 57.2 % of the time (495 of 865 patient days observed) prior to the intervention and 72.0% of the time (622 of 864 patient days observed) during the intervention. These identified a significant increase in all categories of care rituals from usual care to intervention phases ($p < 0.05$ in all cases) with notable increases in the use of personal care from 16.9% (CI 12.8–21.1) to 45.2% (CI 39.6–50.8), sight from 6.1% (CI 3.3–8.9) to 26.9% (CI 21.5–32.2), taste from 13.3% (CI 9.0–17.7) to 31.7% (CI 25.6–37.8), and touch from 34.7% (CI 29.3–40.2) to 63.7% (CI 58.2–69.3) (Figure 3).

Primary Outcome-Symptoms of PTSD at 90 days

At 90 day follow-up in the usual care group (N=130), 39.2% (CI 30.7–47.4) of family members had IES-r scores greater than or equal to 30, identifying important symptoms of PTSD. After introducing FCR, at 90 day follow-up (N=129), 27.1% (CI 19.2–35.1) had IES-r greater than or equal to 30, a significant reduction in family members with symptoms of PTSD (adjusted OR of 0.54, CI 0.30–0.98, $p = 0.041$) (Table 2).

Secondary outcomes (Table 2)

Symptoms of Depression and Anxiety—There was no difference in symptoms of depression between the usual care (N=131, 26.5%, CI 18.8–34.3) and intervention groups (N=129, 25.2%, CI 17.4–33.1) with an adjusted OR of 0.92 (CI 0.51–1.66, $p = 0.787$). Comparing the change in enrollment scores to 90 day follow-up calls, there was a non-significant decrease ($p = 0.068$) in depression scores at 90 day follow-up in the intervention group (–26.7%, CI –35.9– –17.5) compared to usual care (–14.5%, CI –23.7– –5.4).

In the usual care group, 41.0% (CI 32.3–49.6) of family members had a HADS anxiety score 8 at 90 day follow-up, while 45.5% (CI 36.5–54.4) of family members had the same in the intervention group (adjusted OR of 1.19 (CI 0.70–2.02, $p = 0.519$), a non-significant difference. Comparing the change in enrollment scores to 90 day follow-up calls, there was a significant decrease ($p = 0.019$) in the anxiety scores at 90 day follow-up in the intervention group (–35.7%, CI –45.1– –26.3) compared to usual care (–19.3%, CI –29.2– –9.4).

Family Satisfaction—In the usual care group, the mean FS-ICU24 score of family members was 85.1 (N=126, CI 82.4–87.8) at 90 day follow-up, while in the intervention group mean FS-ICU24 scores at follow-up were 89.0 (N=128, CI 86.2–91.8), which was not statistically different (adjusted difference 2.96, CI –0.67–6.58, $p = 0.110$). There was no significant difference in the mean response to the “satisfied with care question” (adjusted difference –0.08, CI –0.36–0.21, $p = 0.606$). The mean adjusted responses to “included in the decision making” was significantly higher post-intervention by 0.25 (CI 0.04–0.47, $p = 0.021$). For “had control over the care”, the mean adjusted response change was not significant (0.22, CI –0.6–0.51, $p = 0.124$).

Geometric Mean Patient Length of Stay, ICU Mortality, Code Status Change—

There was no statistical difference in geometric mean patient LOS at 4.9 days vs 5.4 days (adjusted ratio of 1.16, CI 0.97–1.40 $p=0.110$). Adjusted patient ICU mortality was not statistically different between the two groups (OR 1.22, $p=0.503$). Additionally, adjusted occurrence of code status change was not statistically significantly different between the groups (OR 1.27, $p=0.411$).

Palliative Care and Spiritual Care Consults—There were significantly more palliative care consults in the usual care phase (21.3%, CI 14.4–28.2) compared to the intervention phase (11.8%, CI 6.2–17.4, adjusted OR 0.43, $p=0.021$). Spiritual care consults were placed statistically significantly more in the usual care group (25.0%, CI 17.7–32.3) compared to the intervention group (8.7%, CI 3.8–13.6, adjusted OR 0.28, $p=0.001$).

Nursing Perception of Impact of Intervention—During the intervention stage, 524 nurses from all three sites completed surveys on their opinion of the intervention and its impact on the care they delivered. For all questions, a response of 1 indicated strongly disagreeing with the statement, a 5 indicated strongly agreeing and a 3 indicated being neutral. The mean response to the statement that the quality of the care they delivered was improved was 3.98 (CI 3.9–4.06) and the mean response to the statement that the intervention did not interfere with their care of the patient was 4.42 (CI 4.34–4.49). Additionally, the mean response to statement that the intervention improved their communication with the family members was 4.0 (3.92–4.08). See the Supplementary Figure 3 for full results of the nursing surveys.

DISCUSSION

The stress-related symptoms that family members incur from the experience of having a loved one admitted to the ICU are well-documented (1–2, 8–10, 28). While previous studies have targeted physician, nurse, and social work focused interventions and communication strategies with variable success (22, 29–31), to our knowledge no previous study has evaluated strategies for providing opportunities for family members to be involved in the care of adult patients with the goal of reducing these stress-related symptoms. We conducted a prospective, multicenter, multinational, before-and-after trial with the hypothesis that engaging families would reduce symptoms of PTSD at 90 days post-death or discharge from the ICU. The intervention was associated with a significant reduction in PTSD symptoms in the family members and a significant a reduction in anxiety scores from enrollment to 90 days. Overall family satisfaction demonstrated a trend towards a positive relationship between FCR and satisfaction. Moreover, family members identified being included in the decision making process more often in the intervention. Finally, there was a significant reduction in the use of palliative care and spiritual care services.

There are several strengths in the design of this study. First, the multicenter, multinational design with very few exclusion criteria suggests the results may apply to the family members of a wide variety of patients admitted to medical or medical/surgical ICU's who are at high risk of dying. Additionally, by engaging the nurses, this study identified the care practices employed by families prior to the intervention and identified that, in all cases, the

care rituals increased during the intervention stage. This increase in family care practices supports the hypothesis that the reduction in symptoms of PTSD may be associated with the intervention rather than a different temporal change unrelated to the intervention. Also, based on nurses' responses to surveys, it seems that the intervention did not interfere with nursing work flow, and that many nurses reported appreciating the family participation, an important consideration when operationalizing a bedside intervention such as this.

There are, however, several important limitations in the design that may have impacted the results. First, this is a before-and-after intervention trial and there likely were unmeasured confounders between the groups that limit the interpretation of the results. Second, the enrollment times at each site were different, specifically at the two US sites.

The planned 6-month recruitment times during the after phase at the three sites varied because of staffing issues at one site resulting in early termination of the study (3 months) and requiring extended recruitment at other sites (12 months). This difference seems unlikely have introduced bias, although we cannot exclude this possibility. Additionally, subgroup analyses suggest that the significant reduction in symptoms of PTSD may be largely driven by the Italian site (Supplementary Figure 4). This may suggest important cultural differences in practice that could influence responses to an intervention such as FCR. Interestingly, though the PTSD symptom reduction was primarily at the Italian site, the significant reduction in palliative and spiritual care consults was at the two US sites. Although this reduction may be a negative unintended consequence given the literature of its importance in ICU care, this finding may also represent the meeting of family members' palliative needs through primary palliative care provided by the ICU team (32) or possibly associated with the intervention supporting previously unmet palliative needs of the patients and their families. Finally, the enrollment was largely white and female family members, which may limit the generalizability of these results.

Conclusion

In this study, engaging family members in Family Care Rituals, an intervention designed to empower family members to participate in the care of their loved ones in the intensive care unit, was associated with reduced symptoms of PTSD 90 days after death or discharge of the patient from the ICU. Moreover, the intervention was able to be safely implemented and did not interfere with nursing care. These findings suggest that there are opportunities to evaluate family-support interventions such as this in a randomized trial to identify ways to improve family outcomes for patients admitted to the ICU.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements

We would like to acknowledge the ICU nurses, research staff, and physicians at each site, as well as the participants of the study. Additionally, Gary Phillips, MAS provided paid statistical consultation and generated statistical models for the results

Research completed at following institutions: Rhode Island Hospital, Rush Medical Center, Azienda Ospedaliero-Universitaria Careggi

Financial Support: The James M Cox Foundation provide support for this trial in the form of grant funding for study coordination, travel, supplies and statistical analysis, but had no role in study design, data collection and analysis, decision to publish or preparation of the manuscript. The corresponding author is further supported by NHLBI Grant: T32 HL134625

Copyright form disclosure: Dr. Amass's institution received funding from the National Heart, Lung, and Blood Institute (grant T32 HL134625) and he received support for article research from the National Institutes of Health. Drs. Amass, OMahoney, Caine, and Palmisciano's institutions received funding from the James M. Cox Foundation. Dr. Villa received funding from Baxter and Pall. Dr. OMahoney received support for article research from the Family Foundation Grant. Drs. McFadden, Walsh, Caine, and Palmisciano received support for article research from James M. Cox Foundation. Dr. De Gaudio's institution received funding from MSD Italia and Pall, and he received funding from Baxter.

References

1. Davidson JE, Jones C, Bienvenu OJ: Family response to critical illness: postintensive care syndrome-family. *Crit Care Med*, 2012 40(2): p. 618–24. [PubMed: 22080636]
2. Abbott KH, Sago JG, Breen CM, et al.: Families looking back: one year after discussion of withdrawal or withholding of life-sustaining support. *Crit Care Med*, 2001 29(1): p. 197–201. [PubMed: 11176185]
3. Azoulay E, Chevret S, Leleu G, et al.: Half the families of intensive care unit patients experience inadequate communication with physicians. *Crit Care Med*, 2000 28(8): p. 3044–9. [PubMed: 10966293]
4. Harvey MA: Evolving toward--but not to--meeting family needs. *Crit Care Med*, 1998 26(2): p. 206–7. [PubMed: 9468150]
5. Heyland DK, Rocker GM, O'Callaghan CJ, et al.: Dying in the ICU: perspectives of family members. *Chest*, 2003 124(1): p. 392–7. [PubMed: 12853551]
6. Lynn J, Teno JM, Phillips RS, et al.: Perceptions by family members of the dying experience of older and seriously ill patients. SUPPORT Investigators. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments. *Ann Intern Med*, 1997 126(2): p. 97–106. [PubMed: 9005760]
7. Malacrida R, Bettelini CM, Degrate A, et al.: Reasons for dissatisfaction: a survey of relatives of intensive care patients who died. *Crit Care Med*, 1998 26(7): p. 1187–93. [PubMed: 9671367]
8. Molter NC: Needs of relatives of critically ill patients: a descriptive study. *Heart Lung*, 1979 8(2): p. 332–9. [PubMed: 253712]
9. Pochard F, Azoulay E, Chevret S, et al.: Symptoms of anxiety and depression in family members of intensive care unit patients: ethical hypothesis regarding decision-making capacity. *Crit Care Med*, 2001 29(10): p. 1893–7. [PubMed: 11588447]
10. Matt B, Schwarzkopf D, Reinhart K, et al.: Relatives' perception of stressors and psychological outcomes - Results from a survey study. *J Crit Care*, 2017 39: p. 172–177. [PubMed: 28273613]
11. Shrank WH, Kutner JS, Richardson T, et al.: Focus group findings about the influence of culture on communication preferences in end-of-life care. *J Gen Intern Med*, 2005 20(8): p. 703–9 [PubMed: 16050878]
12. Muni S, Engelberg RA, Treece PD, et al.: The influence of race/ethnicity and socioeconomic status on end-of-life care in the ICU. *Chest*, 2011 139(5): p. 1025–1033. [PubMed: 21292758]
13. Engstrom A, Soderberg S: The experiences of partners of critically ill persons in an intensive care unit. *Intensive Crit Care Nurs*, 2004 20(5): p. 299–308; quiz 309–10. [PubMed: 15450619]
14. McAdam JL, Arai s, Puntillo KA: Unrecognized contributions of families in the intensive care unit. *Intensive Care Med*, 2008 34(6): p. 1097–101. [PubMed: 18369593]
15. Davidson JE: Family-Centered Care: Meeting the Needs of Patients' Families and Helping Families Adapt to Critical Illness. *Crit Care Nurse*. 2009 29: p. 28–34 [PubMed: 19487778]
16. Davidson JE, Aslakson RA, Long AC, et al. Guidelines for family-centered care in the neonatal, pediatric, and adult ICU. *Crit Care Med*. 2017;45:103–128. [PubMed: 27984278]

17. Lee MD, Friedenber AS, Mukpo DH, et al.: Visiting hours policies in New England intensive care units: strategies for improvement. *Crit Care Med*, 2007 35(2): p. 497–501. [PubMed: 17205012]
18. Rocker G, Cook D, Sjøkvist P, et al.: Level of Care Study Investigators. Canadian Critical Care Trials Group. Clinician predictions of intensive care unit mortality. *Crit Care Med*. 5 2004;32(5):1149–1154. [PubMed: 15190965]
19. Cook D, Rocker G, Marshall J, et al.: Withdrawal of Mechanical Ventilation in Anticipation of Death in the Intensive Care Unit. *NEJM*. 9 18 2003; 349(12):1123–1132 [PubMed: 13679526]
20. Sundin EC, Horowitz MJ. Horowitz's Impact of Event Scale: evaluation of 20 years of use. *Psychosom Med* 2003 65: p. 870–6. [PubMed: 14508034]
21. Sundin EC, Horowitz MJ: Impact of Event Scale: psychometric properties. *Br J Psychiatry*, 2002 180: p. 205–9. [PubMed: 11872511]
22. Lautrette A, Darmon M, Megarbane B, et al.: A communication strategy and brochure for relatives of patients dying in the ICU. *N Engl J Med*, 2007 356(5): p. 469–78. [PubMed: 17267907]
23. Pochard F, Azoulay E, Chevret S, et al.: Symptoms of anxiety and depression in family members of intensive care unit patients: ethical hypothesis regarding decision-making capacity. *Crit Care Med* 2001; 29:1893–7 [PubMed: 11588447]
24. Zigmond AS, Snaith RP: The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica*, 1983 67(6): p. 361–70. [PubMed: 6880820]
25. Wall RJ, Engelberg RA, Downey L, et al.: Refinement, scoring, and validation of the Family Satisfaction in the Intensive Care Unit (FS-ICU) survey. *Crit Care Med*, 2007 35(1): p. 271–9. [PubMed: 17133189]
26. Azoulay E, Pochard F, Kentish-Barnes N, et al.: Risk of post-traumatic stress symptoms in family members of intensive care unit patients. *Am J Respir Crit Care Med*, 2005 171(9): p. 987–94. [PubMed: 15665319]
27. Bjelland I, Krokstad S, Mykletun A, et al.: Does a higher education level protect against anxiety and depression? The Hunt Study. *Social Science and Medicine*, 2008 66(6): p 1334–1345 [PubMed: 18234406]
28. Lilly CM, De Meo DL, Sonna LA, et al.: An intensive communication intervention for the critically ill. *Am J Med*, 2000 109(6): p. 469–75. [PubMed: 11042236]
29. White DB, Angus DC, Shields AM, et al.: A Randomized Trial of a Family-Support Intervention in Intensive Care Units. *N Engl J Med*, 2018 378(25): p. 2365–2375. [PubMed: 29791247]
30. Curtis JR, Treece PD, Nielsen EL, et al.: Randomized Trial of Communication Facilitators to Reduce Family Distress and Intensity of End-of-Life Care. *Am J Respir Crit Care Med*, 2016 193(2): p. 154–62. [PubMed: 26378963]
31. Curtis JR, Nielsen EL, Treece PD, et al.: Effect of a quality-improvement intervention on end-of-life care in the intensive care unit: a randomized trial. *Am J Respir Crit Care Med*, 2011 183(3): p. 348–55. [PubMed: 20833820]
32. Nelson JE, Bassett R, Boss RD, et al.: Models for structuring a clinical initiative to enhance palliative care in the ICU: A report from the Improve Palliative Care in the ICU (“IPAL-ICU”) Project and the Center to Advance Palliative Care. *Critical Care Medicine*, 2010; 38: p.1765–1773. [PubMed: 20562699]

Figure 1-. Family Care Rituals Domains and Suggested Options-

7 domains of family care rituals with suggested options for engagement within each domain

*only occurred at Rush Medical Center

**One patient stated it was too stressful to complete IES-r, counted as IES>30 (symptoms of PTSD) for analysis, and they did not complete FSICU-24

ICU= Intensive Care Unit; CMO= Comfort Measures Only; ICU LOS= ICU Length of Stay; HADS= Hospital Anxiety and Depression Scale; FS-ICU24= Family Satisfaction in the ICU-24 item questionnaire; IES-r= Impact of Events Scale- revised

Figure 2-- Screening and Follow Up-
Flow diagram for usual care and intervention screening and enrollment, including reasons for exclusion and those included for final analysis

Domain:	Suggestions:
Sense of smell	☐ Bring in a small bowl of the patient's favorite food to fill the room with its aroma. ☐ Apply essential oils, brought from home, to areas of the skin approved by the patient's nurse. ☐ Apply scented eye or head pillows. ☐ Bring in the patient's favorite blanket or pillow from home.
Sense of sound	☐ Bring in audio of the patient's favorite music or soothing nature sounds. ☐ Bring in audio or video of a cherished event in the patient's life.
Sense of touch	☐ Apply soothing massage to areas of the patient's body, approved by his/her nurse. ☐ Apply lotions to areas of the patient's body, approved by his/her nurse. ☐ Regularly freshen or fluff the patient's pillow for comfort. ☐ Hold the patient's hand while visiting.
Sense of taste	☐ Apply a cool wet wash cloth to the patient's lips, eyes or forehead. ☐ Apply glycerin oral swabs to the patient's lips. ☐ Apply soup, by an oral swab to the patient's lips, when allowed by the nurse.
Sense of sight	☐ Bring from home personal objects for their hospital room, such as pictures, blanket, pillow etc. ☐ Bring from home the patient's notes, cards or personal artwork.
Personal care	<p>(all with assistance and education from the patient's nurse)</p> ☐ Apply oral suctioning. ☐ Assist with turning and positioning. ☐ Freshen the patient's pillow. ☐ Collect additional blankets from the storage closet as needed. ☐ Apply a cool wash cloth to mouth, eyes or head.
Spiritual	☐ Read excerpts to the patient from their favorite book, poem or religious passage. ☐ Read to the patient from a collection of spiritual readings. ☐ Bring pictures from home and tell the story of each picture to the patient. ☐ Display religious symbols, in the form of icons/statues, images or protective jewelry.

Figure 3—. Nursing Recorded Observations of Family Engagement, by Domain—nursing recorded frequency (%) of family participation in bedside care by domain, comparing usual care to intervention phase.

Table 1–**Patient and Family Demographics**

Patient Demographics	Usual Care (N=136)	Intervention (N=127)	p-value
Mean Age (range)	64.7 (19.0–91.3)	64.5 (20.7–98.1)	0.915
Gender (n, % female)	61 (44.9)	65 (51.2)	0.305
Race (%)			
White	97 (71.2)	105 (82.7)	0.040
Black or African American	23 (16.9)	9 (7.1)	
Other	16 (11.8)	13 (10.2)	
Mean APACHE II score [*] (range)	24.9 (6–51)	24.2 (4–51)	0.622
Admission Diagnosis ^{**} (%)			
Neurologic	11 (8.1)	12 (9.4)	0.696
Respiratory	46 (33.8)	37 (29.1)	0.414
Respiratory Failure/Pneumonia	35	28	
Cardiac	17 (12.5)	23 (18.1)	0.204
Cardiac Arrest	7	10	
Infectious	26 (19.1)	18 (14.2)	0.283
Gastrointestinal/Renal	10 (7.4)	18 (14.2)	0.073
Hematologic/Oncologic	20 (14.7)	18 (14.2)	0.902
Postoperative	15	14	
Family Demographics	Usual Care (N=226)	Intervention (N=226)	
Mean Number Enrolled per Patient (range)	1.67 (1–6)	1.77 (1–5)	0.363
Mean Age (range)	52.8 (18.5–89.9) ^{***}	51.0 (19.9–87.0)	0.206
Gender (n,% female)	151 (66.8)	148 (65.5)	0.766
Race (%)			
White	170 (75.2)	184 (81.4)	0.098
Black or African American	31 (13.7)	17 (7.5)	
Other	25 (11.1)	25 (11.1)	
Country of Birth (%) ^{****}			
United States	151 (67.1)	156 (69.3)	0.096
Italy	46 (20.4)	51 (22.7)	
Central or South America	12 (5.3)	7 (3.1)	
Europe (not Italy)/Asia/Africa	16 (7.1)	11 (4.9)	
Level of Education (%)			
Elementary or less	26(11.5)	26 (11.5)	0.714
High School	91 (40.3)	96 (42.5)	
College/University/Advanced Degree	109 (48.2)	104 (46.0)	
Relationship to Patient (%)			
Spouse/Significant Other	48 (21.2)	58 (25.7)	0.160

Patient Demographics	Usual Care (N=136)	Intervention (N=127)	p-value
Parent/Child	116 (51.3)	104 (46.0)	
Sibling/Other Relative	41 (18.2)	54 (23.9)	
Friend	21 (9.29)	10 (4.4)	

* APACHE II score within first 24 hours in the intensive care unit, usual care N=123 and Intervention N=125, lower due to missing clinical data

** Most common diagnosis listed per category

*** 2 family members with missing age data, N=224

**** 1 family member with missing country of birth in both phases, N=225

Table 2--

Results

Outcome	Usual Care	Intervention	Unadjusted OR	p value	Adjusted OR [^]	p value
Primary Outcome						
Symptoms of PTSD at 90 day follow-up *	39.2 (30.6–47.8)	27.1 (19.2–35.1)	0.58 (0.34–0.99)	0.046	0.54 (0.30–0.98)	0.041
Secondary Outcomes						
Symptoms of Depression *						
90 day follow-up at enrollment	26.5 (18.8–34.3)	25.2 (17.5–33.3)	0.93 (0.52–1.66)	0.818	0.92 (0.51–1.66)	0.787
enrollment to day 90	41.1 (34.1–48.0)	51.9 (44.8–59.0)	1.55 (1.03–2.32)	0.034	1.57 (1.03–2.40)	0.035
Symptoms of Anxiety *						
90 day follow-up at enrollment	–14.5 (–23.7 – –5.4)	–26.7 (–35.9 – –17.5)		0.068		
enrollment to day 90						
Family Satisfaction (mean score) **						
90 day follow-up at enrollment	41.0 (32.3–49.6)	45.5 (36.5–54.4)	1.20 (0.72–2.00)	0.479	1.19 (0.70–2.02)	0.519
enrollment to day 90	60.3 (53.4–67.1)	81.2 (75.6–86.7)	2.84 (1.79–4.50)	< 0.001	2.89 (1.79–4.66)	< 0.001
Total Score	–19.3 (–29.2 – –9.4)	–35.7 (–45.1 – –26.3)		0.019		
Satisfied with the Care						
Included in the Decision Making	85.1 (82.4–87.8)	89.0 (86.2–91.8)	3.85 (–0.03–7.73)	0.052	2.96 (–0.67–6.58)	0.110
Had Control Over the Care	4.2 (4.0–4.4)	4.1 (3.9–4.3)	–0.08 (–0.38–0.22)	0.589	–0.08 (–0.36–0.21)	0.606
Geometric mean Length of Stay (days) ***						
ICU mortality	4.4 (4.3 – 4.6)	4.7 (4.6 – 4.9)	0.26 (0.05–0.47)	0.016	0.25 (0.04–0.47)	0.021
Occurrence of Code Status Change	3.9 (3.7 – 4.2)	4.3 (4.0 – 4.5)	0.32 (0.01–0.62)	0.042	0.22 (–0.6–0.51)	0.124
Palliative Care Consult	4.9 (4.3–5.5)	5.4 (4.7–6.1)		0.304	1.16 (0.97–1.40)	0.110
Spiritual Care Consult	25.7 (18.4–33.1)	26.0 (18.4–33.6)	1.01 (0.58–1.76)	0.963	1.22 (0.68–2.21)	0.503
	32.4 (24.5–40.2)	35.4 (27.1–43.8)	1.15 (0.69–1.91)	0.598	1.27 (0.72–2.23)	0.411
	21.3 (14.4–28.2)	11.8 (6.2–17.4)	0.49 (0.25–0.97)	0.041	0.43 (0.21–0.88)	0.021
	25.0 (17.7–32.3)	8.7 (3.8–13.6)	0.28 (0.14–0.59)	0.001	0.28 (0.13–0.59)	0.001

[^] Adjusted for patient age, patient gender, APACHE score>20, family gender, family level of education, family location of birth

* 90 days post ICU discharge (IES-r 30 or HADS>8 for depression or anxiety score)

** random effects linear regression, difference in means instead of OR

Ratio of geometric means instead of OR

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