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Author manuscript

Am J Crit Care. Author manuscript; available in PMC 2017 November 01.

Published in final edited form as:

Am J Crit Care. 2016 November ; 25(6): 498–507. doi:10.4037/ajcc2016730.

The Family Navigator: A pilot intervention to support intensive care unit family surrogates

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Abstract

Background—Although communication problems between family surrogates and intensive care unit (ICU) clinicians have been documented, there are few effective interventions. Nurses have the potential to play an expanded role in ICU communication and decision making.

Objectives—To conduct a pilot randomized controlled trial of the Family Navigator (FN), a distinct nursing role to address family members' unmet communication needs early in an ICU stay.

Methods—An inter-disciplinary team developed the FN protocol. A randomized controlled pilot intervention trial of the FN was performed in a tertiary referral hospital ICU to test the feasibility and acceptability of the intervention. The intervention addressed informational and emotional communication needs through daily contact using structured clinical updates, emotional and informational support modules, family meeting support and follow-up phone calls.

Results—Twenty-six surrogate/patient pairs (13 per study arm) were enrolled. Surrogates randomized to the intervention had contact with the FN 90% or more of eligible patient days. All surrogates agreed or strongly agreed that they would recommend the FN to other families. Open-

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ended comments from both surrogates and clinicians were uniformly positive. For both groups, 100% of baseline data collection interviews and 81% of 6–8 week follow-up interviews were completed.

Conclusions—A fully integrated nurse empowered to facilitate decision making is a feasible intervention in the ICU setting. It is well-received by ICU families and staff. A larger randomized controlled trial is needed to demonstrate an impact on important outcomes, such as surrogate well-being and decision quality.

Keywords

communication; decision making; family; palliative care; family support

INTRODUCTION

In the intensive care unit (ICU), family members are thrust into a highly stressful and often bewildering environment. Although good communication is essential to decision making, up to one third of family members of seriously ill patients report problems communicating with clinicians,¹ and clinician/family conflict.^{2,3} Fragmented relationships and unmet needs for communication and emotional support are common.⁴ Family Surrogate Decision Makers (SDMs) often experience high levels of posttraumatic stress,^{5,6} decisional conflict⁷ and regret.⁷ Thus, interventions to improve communication are needed to support family members of critically ill patients in the ICU.

Intervention studies have had limited success in improving communication with SDMs. A systematic review of 16 ICU interventions found that printed information, palliative and ethics consultations and structured communication by the ICU team impacted patient care and family distress.⁸ However, most of these approaches require either resource-intensive consulting teams with expertise in ethics^{9,10} or palliative care,^{11–13} or changing physician behavior (e.g., early family meetings for patients who are expected to die).^{14,15}

We believe nurses have high potential to improve communication through early intervention with SDMs if they are fully integrated into the interdisciplinary ICU team and empowered to facilitate decisions. This strategy is consistent with Institute of Medicine recommendations for expanding nurses' roles in patient care.¹⁶ A major prior effort to develop nursing-led intervention, the SUPPORT study, did not show an impact on patient-centered outcomes such as time to do not resuscitate (DNR) orders, life-sustaining interventions, or pain.¹⁷ The SUPPORT nurses often provided extensive communication, education and emotional support to patients and families, the impact of which may not have been measured by the planned outcomes.¹⁸ Failure to fully integrate into systems of care may have also reduced the impact of the intervention.¹⁹

In recent years, several nurse-focused ICU interventions have showed potential in single arm,²⁰ retrospective analysis²¹ or quasi-experimental (baseline/intervention) studies.^{22–25} One randomized controlled trial of a family meeting facilitator reported improvements in some measures of SDM well-being and decreased length of stay, providing early evidence that nurse interventions have the potential to impact outcomes.²⁶

We describe the development and randomized pilot testing of the Family Navigator (FN), a distinct nursing role to address family members' unmet communication needs early in ICU hospitalization. The goals of this pilot study were to develop the intervention based on our conceptual model, demonstrate feasibility and acceptability, and provide evidence for the feasibility of a future randomized controlled trial to assess impact on family distress.

Conceptual Model

Based on a review of the literature²⁷ and our prior empirical research,^{28,29} we have developed a conceptual model proposing that communication quality impacts decision making, which in turn impacts outcomes for patients and SDMs (Figure 1). Consistent with prior theoretical work in communication,³⁰ we proposed that there are two core dimensions to surrogate/clinician communication: 1) an information dimension; and 2) an emotional dimension. Just as most patients desire to be fully informed about their own medical conditions and decisions in order to make decisions and know what to expect,^{31,32,33} SDMs also describe a preference for early and frequent information.²⁹ Other studies have found that emotional support through empathic statements,³⁴ respect^{35,36} and spiritual support^{37,38} are important.

Cognitive³⁹ and emotional processing⁴⁰ theories of posttraumatic stress disorder (PTSD) propose that when experiencing a trauma, some individuals develop negative appraisals about the situation and about their own capacity to cope with it."⁴¹ In the ICU setting, family decision makers are often overwhelmed by a family member's critical illness. Fear reactions may further reduce the individual's ability to process information.⁴⁰ Specific goals of early intervention include improving functional capacity, encouraging supportive coping mechanisms and optimizing social support.⁴² We theorize that the FN intervention will help individuals cope with the trauma of critical illness by supporting understanding of complex information, providing emotional support and supporting the surrogate's coping mechanisms,⁴² leading to higher quality decisions and better SDM outcomes.

METHODS

The study was approved by our University Institutional Review Board.

Intervention Development

Development Process—The interdisciplinary team, including research staff (nurse researcher, principal investigator, research coordinator, and research assistant (RA)) and ICU staff (physician director, nurse manager, social worker), met weekly for three months to develop the FN intervention. The full investigator team met monthly to oversee implementation. The study was presented at nursing and physician ICU staff meetings early in development to obtain buy-in and input on study design.

Setting and Participants

The study was conducted in an 18 bed ICU located in a tertiary referral hospital. We chose to focus the intervention on patients with severe cognitive impairment because their family members would need to be entirely responsible for decision making, which has been

associated with high distress.⁵ Patient eligibility criteria were: (1) 21 years and older; (2) admitted to the Medical ICU (MICU) team; (3) severe cognitive impairment determined by chart review (sedated or comatose) or a score of 8 or more errors on the Short Portable Mental Status Questionnaire, indicating severe impairment;⁴³ and (4) ability to contact the patient's SDM within 3 days of ICU admission. Patients were excluded if they were imminently dying or were expected to be transferred out of the ICU within 24 hours of admission. SDMs were eligible if they were the legally authorized decision makers based on a Health Care Power of Attorney document or Indiana Surrogate Decision Making Law⁴⁴ and could complete oral or written surveys in English.

Recruitment and randomization

Eligible patients were identified Monday through Friday, between October, 2013 and March, 2014. The RA identified the legally authorized SDM from the medical record or calls to the physician or bedside nurse and contacted the SDM to describe the study, obtain informed consent, and conduct a baseline interview. The research coordinator then randomized each participant using sequentially numbered opaque envelopes that contained the randomly generated group assignment and contacted each SDM to inform them of group assignment.

FN Interventionist Training—The FN Interventionist was an experienced ICU registered nurse who underwent a two-week training period. This included shadowing staff members (nurse manager, clinical director, social worker, and chaplain) to learn how their roles would complement each other, review of the research protocol, study materials, and related literature. The FN also met regularly with the principal investigator and nurse researcher to review materials and refine the FN role and underwent a half day training session based on the VitalTalk⁴⁵ method, led by a trained facilitator (GB).

The Intervention—We mapped the two core communication elements of our conceptual model into the specific interventions performed by the FN (Figure 2). The study involved preset meetings and modules to ensure reproducibility, but at all times the FN was encouraged to tailor responses to individual informational and emotional needs.

FN/SDM Introductory Meeting: The FN met with the SDM decision maker within 24 hours of enrollment, either at the hospital or by phone, to establish a relationship and to assess SDMs needs that would trigger study protocols for informational and emotional support.

Structured Daily Contact: The FN contacted the SDM 5 days per week. The FN participated in daily ICU rounds and completed a structured form to guide daily family communication, including patient status, goals of care, and clinical plan for the day. We established a goal of communication with family SDMs 90% of weekdays. The physician, social worker or other clinicians were encouraged to maintain their usual level of contact with families.

Informational/Emotional Support Modules: Based on our group's prior family care management research,^{46,47} we developed 13 support modules involving an oral script

delivered by the FN and a handout that was left with SDMs. Modules were triggered by clinical findings or SDM needs and addressed the primary domains of SDM knowledge and emotional support.

Family Meetings: The FN identified the need for family meetings based on a major decline in the patient's condition, clinician concern that the patient would not survive ICU stay, assessment of family/SDM need, or physician, social worker or family recommendation. Family meetings were also requested by physicians and the social worker, consistent with standard practice in this ICU. The role of the FN at the meeting was (1) to monitor and facilitate understanding of clinical information and (2) to provide emotional support using the VALUE framework, an approach to guide ICU conversations that includes the following five communication behaviors: Value, Acknowledge, Listen, Understand Elicit.⁴⁸

Post-discharge Phone calls: The FN contacted the SDM at 3 days and at 2 weeks after ICU discharge to assess for any unmet informational or emotional needs and responded to unmet needs with referrals to appropriate hospital resources.

Control Group—The control group received usual care. All enrolled patients were eligible to receive support resources available in this ICU. The ICU social worker provided ongoing, in-depth psychosocial support to all families and coordinated most family meetings, and board certified chaplains provided spiritual care.

Data Collection and Outcomes

We defined feasibility to include the successful implementation of the intervention with high treatment fidelity.⁴⁹ Treatment fidelity measures were selected based on the NIH Treatment Fidelity Working Group.⁵⁰ Fidelity of provider training was addressed by monitoring the FN's completion of the 80 hour training program, ensuring skill acquisition by observing the FN in standardized role plays, and monitoring drift in provider skill through direct observation by the nurse researcher. We assessed fidelity to treatment delivery by measuring percent of eligible subjects completing enrollment interviews, percent of days with medical team contact and SDM contact, number of educational/support modules delivered, and percent follow-up calls completed. The FN also kept a daily online journal. These were reviewed at weekly team meetings. We used REDCap⁵¹ databases to track treatment delivery data.

We operationalized acceptability of recruitment, randomization, and the intervention based on successful participant enrollment, high rates of completion of study measures, low rates of drop out and loss to follow-up, and acceptance by SDMs and ICU clinicians based on semi-structured interviews.⁴⁹

At baseline, we computed a measure of illness severity, the Mean Sequential Organ Failure Assessment (SOFA)⁵² for each patient based on chart review. Our primary measure of SDM well-being was posttraumatic stress symptoms, measured by the Impact of Events Scale-Revised (IES-R) 6–8 weeks post ICU discharge (internal consistency by coefficient alpha, 0.96).^{53,54} Decision quality was measured by the Decision Conflict Scale (0.78).⁵⁵ Because SDMs face a variety of potentially stressful decisions, we administered the scale during

weekly interviews for up to 3 decisions experienced by each SDM.⁵⁶ We analyzed the highest Decision Conflict score for each SDM. At 6–8 weeks, we similarly assessed the highest Decision Regret score for each decision (0.95).⁵⁷ Depression and anxiety were measured at 6–8 week follow-up using the Patient Health Questionnaire (PHQ-9; 0.86)⁵⁸ and the Generalized Anxiety Disorder 7 item scale (GAD-7; 0.92).⁵⁸ These measures have been used in multiple prior studies of SDMs.⁵⁹

Data collection interviews were conducted by phone or in-person with the SDM weekly during the ICU stay and 2–7 days post ICU discharge to identify major decisions and measure decision conflict. At 6–8 weeks after ICU discharge, SDM posttraumatic distress, anxiety, depression and decision regret were assessed. The 6–8 week interview included open- and closed-ended questions about the FN for those in the intervention arm. At the conclusion of the study, we conducted semi-structured interviews with 2 clinicians to assess acceptability to clinicians.

Data Analysis

Markers of adherence to treatment protocol are shown as the proportion of successful contacts over the number of potential contact days or opportunities. We dichotomized scores on the IES-R (≥ 22 and <22 ; scores >22 indicate a high risk of clinically important posttraumatic stress⁶⁰). SOFA scores were dichotomized as <11 or ≥ 11 , as scores ≥ 11 confer a mortality of over 80%.⁶¹ We compared categorical variables using Fisher's Exact test, due to low cell counts, and Student's t-tests or Wilcoxon rank-sum tests for continuous variables, depending on the data distribution. Analyses were performed using SAS v9.3 (SAS Institute, Cary, NC). Semi-structured interviews were analyzed by thematic analysis.⁶²

RESULTS

Participants

We enrolled 26 subjects (13 control and 13 intervention), 55% of eligible subjects (Figure 3). The most common reasons for refusal were lack of interest and feeling it was a bad time due to patient condition or family member emotions. Enrolled patients were 58% female, 27% African American (Table 1). At baseline, intervention patients had lower education (11.5 v. 13.5 years, $p=0.052$) but were otherwise similar. Intervention SDMs also had lower education (12.3 (SD 1.5) v. 15.5 (2.6) years, $p=0.001$) and were more likely to be female (30.8 v. 76.9%; $p=0.047$). No significant differences in severity of depression (mean PHQ-9 score 9.1 (5.1) v. 5.2 (5.3), $p=0.073$) or anxiety (GAD-7 score 8.1 (5.6) v. 4.3 (5.2), $p=0.072$) were observed between the groups.

Pilot Feasibility

All intervention SDMs had the Initial FN/SDM Meeting (Table 2). All SDMs had contact with the FN 90% or more of eligible weekdays. "Communicating with your family member" (92.3%) and "coping with stress" (76.9%) were the two most frequently used support modules (Table 2). Twelve subjects (92.3%) had at least one in-person contact and 6 (46.2%) had at least one phone contact.

Based on the nurse researcher observations of two selected cases, the FN demonstrated expert communication skills as outlined in the VALUE framework. The FN was observed to translate complex medical concepts into layman's terms, assess the SDM's understanding of the medical situation, correct misconceptions, and explain key elements of information.

All baseline data collection interviews were completed. We completed 81% of 6–8 week follow-up interviews. We were unable to complete four of the first 12 follow-up interviews early in the pilot project. After modifying our study protocol to allow evening interviews, we missed only one of a remaining 14 possible interviews.

All SDMs agreed or strongly agreed that they would recommend the FN to other families. No SDM agreed that the FN contacted them too often or took up too much time. Semi-structured interviews described benefits of the intervention, “The support and the overall counseling was comforting and gave optimism and relief. She talked to my kids, which helped them relax.” Semi-structured clinician feedback was highly positive. One physician said, “For family members, it helped them understand better what was going on with the (patient). It helped us to establish the goals of care much faster. For staff, it decreased our frustration.”

Outcome measures

There were no significant differences in posttraumatic stress, anxiety, depression, decision conflict, or decision regret between the FN and control groups (Table 3). We repeated the analyses for anxiety and depression controlling for baseline levels and also found no significant differences.

DISCUSSION

We developed a novel intervention to improve family communication in the ICU that was based on theoretical and empirical communication literature and input from an interdisciplinary team of researchers and ICU clinicians. We delivered the intervention to 13 SDMs with high treatment fidelity. Similar to other nurse-led interventions, this pilot study was well-received by SDMs.^{20,21} Our pilot study also demonstrated the feasibility of randomizing patients within the ICU setting, which has been done in few other studies.^{15,26}

We learned several lessons in this feasibility study that will inform future work. First, data collection strategies were successful because they included phone as well as in person approaches., which enhanced the successful completion of our 6–8 week follow-up interviews. Engagement with ICU staff early in the project with weekly meetings addressed ongoing concerns, encouraged buy-in from clinicians and allowed us to trouble shoot problems in real time. Randomization within the ICU was acceptable to SDMs. We minimized contamination by avoiding FN contact with control families and maintain careful control of printed study materials, although a larger study demonstrating differences between the groups will be needed to determine if this concern was adequately addressed.

Our model incorporates several innovations that are important for success in the ICU setting. Rather than simply adding a new resource, the FN is (1) fully integrated into the ICU

clinical team; (2) provided with the authority, responsibility, and resources to facilitate communication; and (3) empowered to deliver interventions directly to the SDM that are jointly agreed-upon with physicians.

Limitations of this work include the small sample size, which prevented the evaluation of between-group differences with adequate power. Although our outcome measures have been validated in patients, there is not validation data from family surrogates. Although decisions occurred throughout the intervention, a detailed analysis of decision conflict and regret that examined changes over time was not feasible given the small sample size in this pilot as it would require controlling for decision type. With a larger sample size, a linear mixed model that would allow for the separation of intervention from treatment decision effects would be more appropriate.

We note that at baseline that although there were no significant differences in depressive symptoms or anxiety, the FN group had baseline scores at least ½ standard deviation higher than the control group. This potential imbalance could also have impacted group comparisons. In future work, we will stratify study randomization by baseline measures in order to reduce potential imbalances between the groups. Our refusal rate was 41%, which is similar to other ICU interventions^{20,26} but may have introduced bias. Loss to follow-up was higher in the intervention group, (4 v. 1 SDM). Although it is possible that this effect was due to the intervention, we note that no SDM withdrew from the intervention itself. Additionally, this intervention was implemented in a single, Midwest tertiary ICU with moderately high health literacy and may not generalize to other settings.

Demonstrating feasibility of this intervention is only the first step. Future work is now needed to show that this highly integrated, novel intervention has an impact on patient and SDM outcomes. Although several small demonstration projects have relied on nurses to enhance communication,^{20,21,25} only one prior randomized controlled studies provides evidence that a nurse intervention improves SDM outcomes.²⁶ Additional research is needed to demonstrate the impact of nursing interventions in this setting. Additionally, this intervention may have an impact on a broader range of patients than the group included in the present study. Future work will be needed to demonstrate this.

Acknowledgments

We wish to acknowledge Susan Elpers RN, BSN, CNML, Joy Dyer, MSW, Wanda Keith, RN and Kenneth Covinsky, MD for their contributions to intervention development and to Mary Austrom, PhD for guidance on family education. Supported by Award Number P30AG024967 from the National Institute on Aging to the IU Roybal Center. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute on Aging or the National Institutes of Health.

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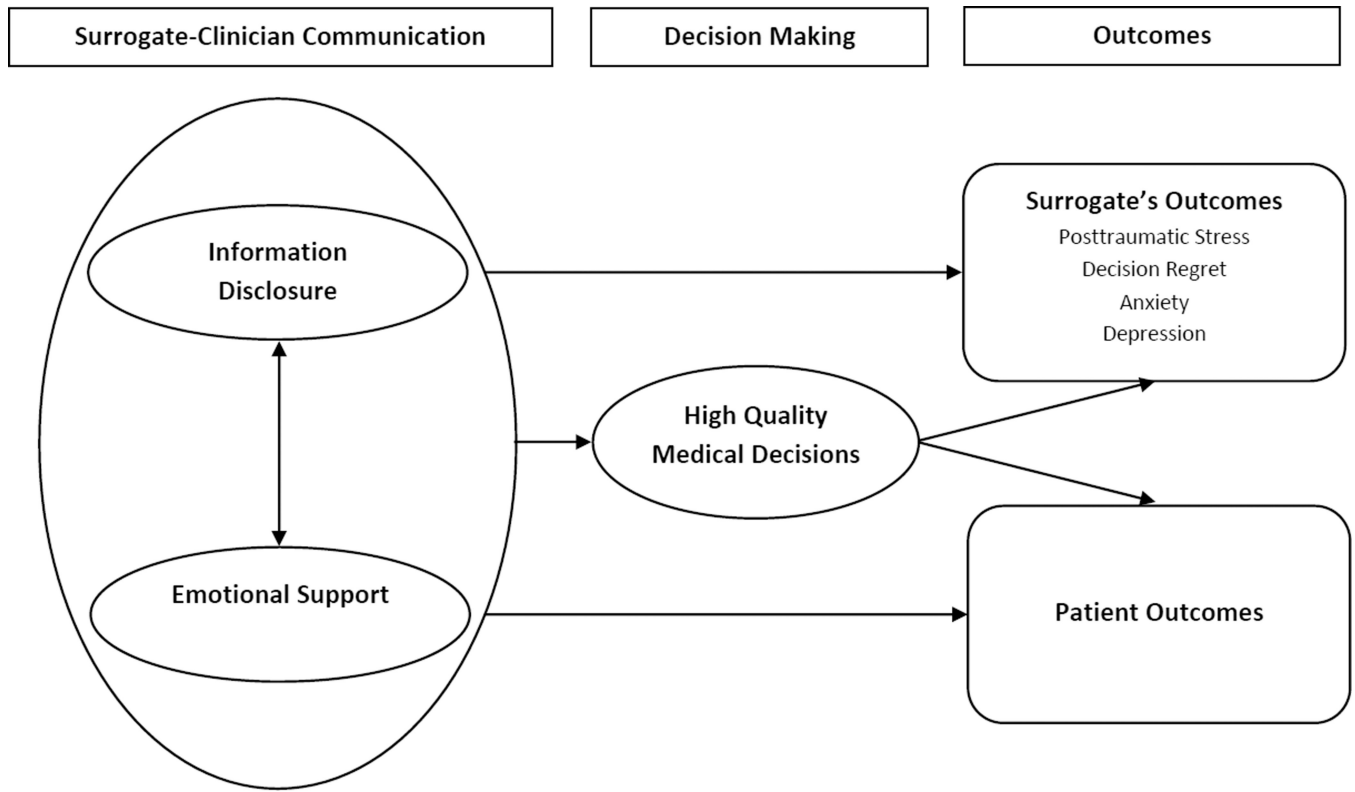


Figure 1.
Conceptual Model

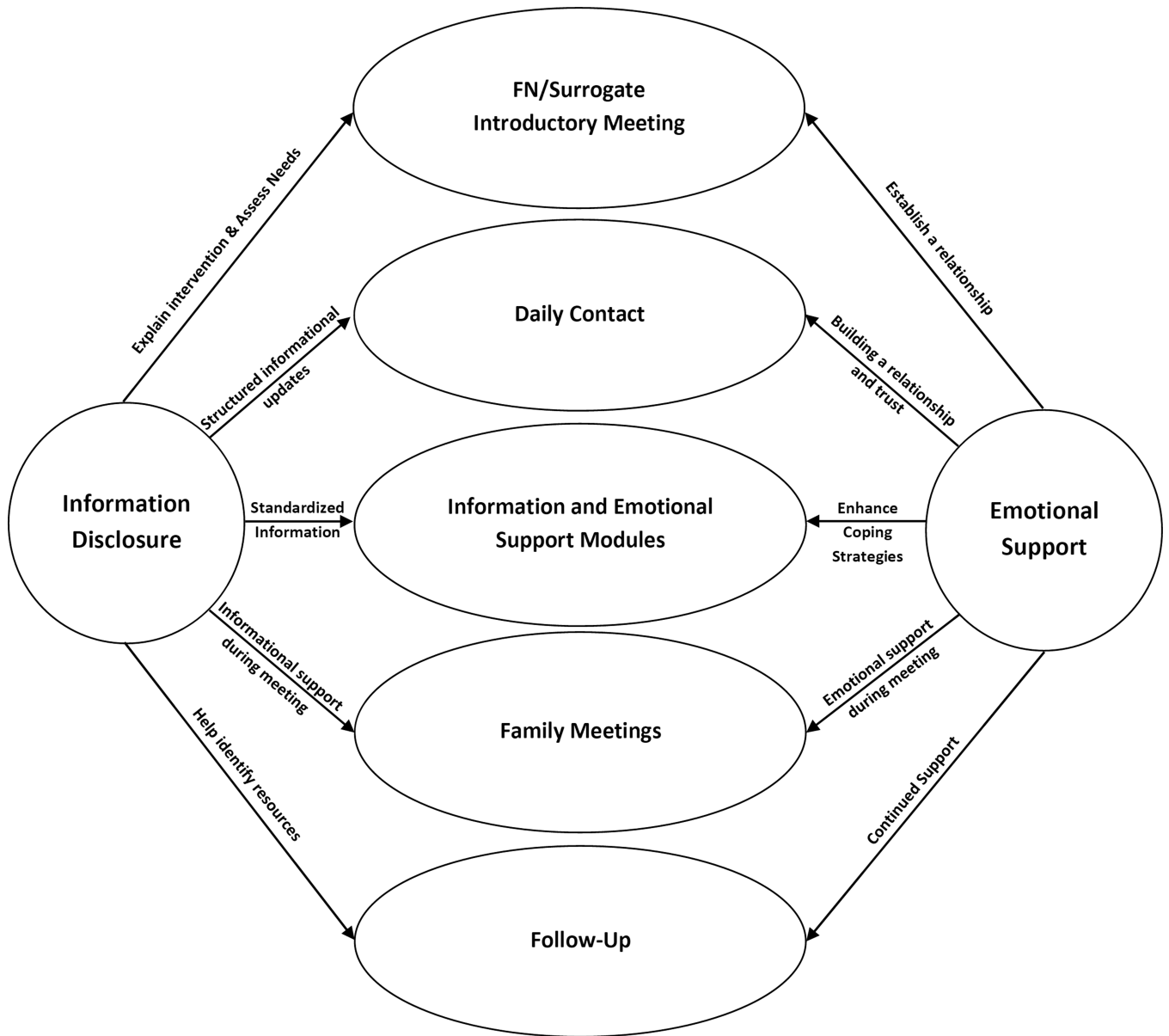


Figure 2.
Model of the Intervention

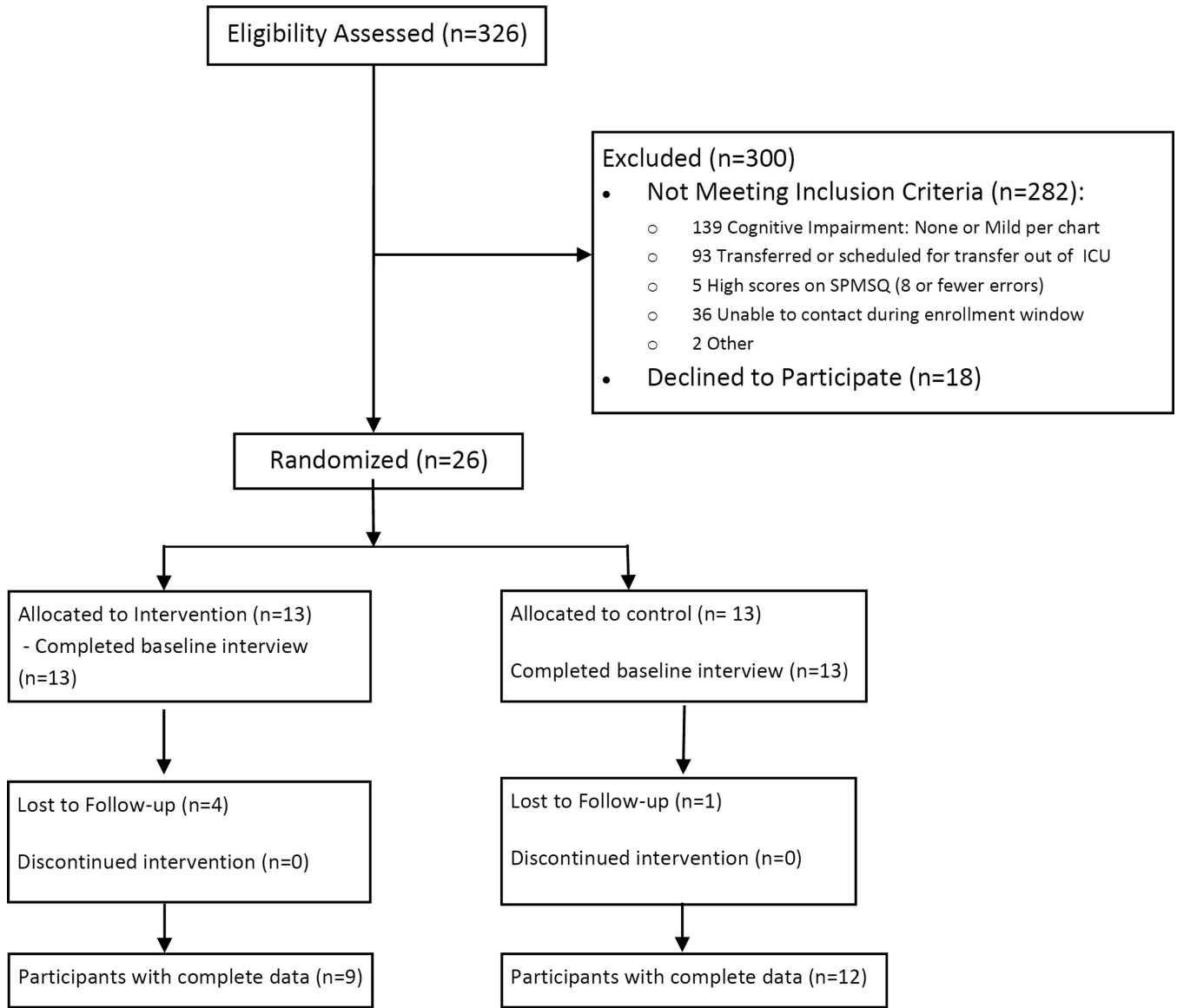


Figure 3.
Screening and Randomization

Table 1

Patient and Surrogate Characteristics

Demographics	Overall	Family Navigator	Control	P-value
Number	26	13	13	
Patient Characteristics				
Mean Patient Age	55.35 (12.62)	53.27 (14.18)	57.42 (11.03)	0.4131
Patient Sex				
Female	15 (57.7)	9 (69.2)	6 (46.2)	0.4283
Patient Race				
African American	7 (26.9)	3 (23.1)	4 (30.8)	1.000
White	19 (73.1)	10 (76.9)	9 (69.2)	
Other	0	0	0	
DK Refused	0	0	0	
Patient Hispanic ethnicity	0	0	0	n/a
Patient Education				
Mean (SD)	12.46 (2.6)	11.5 (1.6)	13.5 (3.1)	0.0525
Median	12	12	14	
Range	6 – 20	8 – 14	6 – 20	
Sequential Organ Failure Assessment (11+)	21 (80.8)	9 (69.2)	12 (92.3)	0.3217
Surrogate Characteristics				
Mean Surrogate Age	48.54 (14.83)	50.93 (12.01)	46.16 (17.36)	0.4233
Relationship to Patient				
Spouse	14 (53.9)	8 (61.5)	6 (46.2)	0.8614
Son/Daughter	8 (30.8)	3 (23.1)	5 (38.5)	
Grandchild	0	0	0	
Other	4 (15.4)	2 (15.4)	2 (15.4)	
Surrogate sex				
Female	14 (53.9)	4 (30.8)	10 (76.9)	0.0472
Surrogate Race				
African American	6 (23.1)	3 (23.1)	3 (23.1)	1.0000
White	20 (76.9)	10 (76.9)	10 (76.9)	
Other	0	0	0	
Hispanic ethnicity	0	0	0	n/a
Marital Status				

Demographics	Overall	Family Navigator	Control	P-value
Married	18 (69.2)	9 (69.2)	9 (69.2)	0.4278
Single	4 (15.4)	1 (7.7)	3 (23.1)	
Divorced	4 (15.4)	3 (23.1)	1 (7.7)	
Widowed	0	0	0	
Education				0.0011
Mean (SD)	13.9 (2.7)	12.3 (1.5)	15.5 (2.6)	
Median	13	12	16	
Range	10 – 21	10 – 16	12 – 21	
Annual household income (\$)				0.5654
Under 24999	11 (44.0)	6 (46.2)	5 (41.7)	
25–49999	7 (28.0)	5 (38.5)	2 (16.7)	
50–74999	2 (8.0)	1 (7.7)	1 (8.3)	
75–99999	3 (12.0)	1 (7.7)	2 (16.7)	
100 or more	2 (8.0)	0	2 (16.7)	
Not answered (Not determined, refused, Don't Know)		0	0	
Depression (PHQ-9)				0.0728
Mean (Standard Deviation (SD))	7.2 (5.5)	9.1 (5.1)	5.2 (5.3)	
Median	7	8	4	
range	0 – 18	1 – 18	0 – 17	
Anxiety (GAD-7)				0.0716 (Wilcoxon)
Mean (SD)	6.2 (5.6)	8.1 (5.6)	4.3 (5.2)	
Median	4.5	5	2	
range	0 – 19	3 – 19	0 – 19	
Health literacy				0.6986 (Wilcoxon)
REALM-SF (n)Number correct				
Mean (SD)	7.3 (0.6)	7.4 (0.7)	7.2 (0.4)	
Median	7	7	7	
Range	7 – 9	7 – 9	7 – 8	

Abbreviations: SD Standard Deviation, PHQ;—Patient Health Questionnaire-9, GAD- Generalized Anxiety Disorder 7 item scale, REALM-SF Rapid Estimate of Adult Literacy in Medicine-Short Form

Table 2

Intervention Delivery (N=13)

Intervention	Num (percent)
Introductory interview complete	13 (100%)
Duration of introductory interview, Mean (SD)	54.55 min (20.18)
Mode	
In person	10 (76.9%)
By phone	3 (23.1%)
Surrogate contacted on greater than 90% of eligible days	13 (100%)
Information/support modules: frequency of use by patient	
Communicating with your family member	12 (92.3%)
Coping with stress	10 (76.9%)
ICU physicians	9 (69.2%)
ICU staff	8 (61.5%)
The Family meeting	6 (46.2%)
Goals of Care	5 (38.5%)
Making a decision	3 (23.1%)
Withdrawal of LST	3 (23.1%)
Code status	2 (15.4%)
Hospice	2 (15.4%)
Average total daily time spend on patient/family (minutes)	
1–15	0
16–30	0
31–45	1 (8.3%)
46–60	2 (16.7%)
61–75	2 (16.7%)
76–90	2 (16.7%)
91–120	3 (25.0%)
More than 120	2 (16.7%)
Mode (for any daily contact)	
In person	12 (92.3%)
By phone	6 (46.2%)
Family Meeting (percent of patients with any)	7 (53.9%)
3–5 day follow-up phone calls complete	13 (100%)

Intervention	Num (percent)
2 week follow-up phone calls complete	13 (100%)

Abbreviations: SD Standard Deviation

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Table 3

Family and patient outcomes

Variable	All	Family Navigator	Control	P value
Percent of completed interviews	80.8% (n=21)	69.2% (n=9)	92.3% (n=12)	
Impact of Events				
0-21	12 (57.1)	5 (55.6)	7 (58.3)	1.0000
22+	9 (42.9)	4 (44.4)	5 (41.7)	
Decision Conflict Scale				
Highest score by patient	31.7 (5.5); 32 (20 – 40)	29.5 (6.0); 31.5 (20 – 37)	34.4 (3.6); 33 (31 – 40)	0.1475
Decision Regret Scale				
Highest score per pt				0.7063
Mean SD	9.7 (5.4)	10.0 (7.7)	9.5 (4.3)	
Median	8	6	9.5	
Range	5 – 24	5 – 24	5 – 20	
PHQ-9 total				0.3437
Mean SD	5.4 (6.0)	7.1 (7.4)	4.2 (4.6)	
Median	3	6	2.5	
Range	0 – 24	0 – 24	0 – 11	
GAD-7 total				0.3218
Mean SD	4.7 (5.3)	5.7 (5.7)	3.9 (5.0)	
Median	3	5	0.5	
Range	0 – 18	0 – 18	0 – 12	