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Facilitating Communication for Critically Ill Patients and their Family Members: Study Protocol for Two Randomized Trials Implemented in the U.S. and France

J. Randall Curtis, MD, MPH[1,*], **Nancy Kentish-Barnes, PhD**[2], **Lyndia C. Brumback, PhD**[3], **Elizabeth L. Nielsen, MPH**[1], **Kathryn I. Pollak, PhD**[4,5], **Patsy D. Treece, RN, MN**[1], **Lisa Hudson, RN**[1], **Gigi Garzio, BA**[1], **Jennifer Im, MSc**[1,6], **Bryan J. Weiner, PhD**[7], **Nita Khandelwal, MD, MS**[8], **Matthieu Resche-Rigon, MD, PhD**[9], **Elie Azoulay, MD, PhD**[2], **Ruth A. Engelberg, PhD**[1]

[1]Cambia Palliative Care Center of Excellence and Division of Pulmonary, Critical Care, and Sleep Medicine, University of Washington, Seattle, WA

[2]AP-HP, Hôpital Saint-Louis, Intensive Care Medicine, Famiréa Research Group, Paris, France

[3]Department of Biostatistics, School of Public Health, University of Washington, Seattle, WA

[4]Department of Population Health Sciences, Duke University

[5]Cancer Prevention, Outcomes, and Survivorship Program, Duke Cancer Institute

[6]Department of Health Services, School of Public Health, University of Washington, Seattle, WA

[7]Department of Global Health, University of Washington, Seattle, WA

[8]Department of Anesthesiology and Pain Medicine, University of Washington, Seattle, WA

[9]Université de Paris, ECSTRRA Team-CRESS-UMR 1153, INSERM and URC Saint-Louis, AP-HP, Hôpital Saint-Louis, Paris, France

Abstract

Background: Critically-ill patients and their families suffer a high burden of psychological symptoms due, in part, to many transitions among clinicians and settings during and after critical illness, resulting in fragmented care. Communication facilitators may help.

Design and Intervention: We are conducting two cluster-randomized trials, one in the U.S. and one in France, with the goal of evaluating a nurse facilitator trained to support, model, and teach communication strategies enabling patients and families to secure care consistent with patients' goals, beginning in ICU and continuing for 3 months.

[*]Corresponding author at: J. Randall Curtis, MD, MPH, Professor of Medicine Cambia Palliative Care Center of Excellence, Box 359762 Harborview Medical Center, University of Washington 325 Ninth Avenue, Seattle, Washington 98104, jrc@u.washington.edu.

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Participants: We will randomize 376 critically-ill patients in the US and 400 in France to intervention or usual care. Eligible patients have a risk of hospital mortality of greater than15% or a chronic illness with a median survival of approximately 2 years or less.

Outcomes: We assess effectiveness with patient- and family-centered outcomes, including symptoms of depression, anxiety, and post-traumatic stress, as well as assessments of goal-concordant care, at 1-, 3-, and 6-months post-randomization. The primary outcome is family symptoms of depression over 6 months. We also evaluate whether the intervention improves value by reducing utilization while improving outcomes. Finally, we use mixed methods to explore implementation factors associated with implementation outcomes (acceptability, fidelity, acceptability, penetration) to inform dissemination. Conducting the trial in U.S. and France will provide insights into differences and similarities between countries.

Conclusions: We describe the design of two randomized trials of a communication facilitator for improving outcomes for critically ill patients and their families in two countries.

Introduction

The impact of critical illness is increasing due to our aging population and advances in effectiveness and availability of critical care.[1,2] Critically ill patients and their families suffer a high burden of symptoms of depression, anxiety, and post-traumatic stress due, in part, to fragmented medical care that is often poorly aligned with patients' goals.[3–6] Fragmented care may arise from the numerous transitions patients and families experience across clinicians and settings, starting in the ICU and extending to acute care, often including returning to the ICU as well as transitioning to inpatient rehabilitation, skilled nursing facilities, or home.[7–9] Through these transitions, patients and families often struggle to navigate the spectrum of goals of care to match their goals with treatments, communicate goals to their clinicians, and make difficult medical decisions. Unfortunately, poor communication compounds an already stressful experience.[1,2,7,8,10–14] and can lead to high intensity and unwanted care.[15,16] Ineffective communication has been documented in many countries, including U.S. and France, and differences between these countries have been described.[17] We are testing whether an intervention to improve communication for critically ill patients and their families can reduce family distress in the U.S. and France.

Building on social cognitive theory[18–21] and our prior work,[3,22] we designed an intervention to improve outcomes for patients' family using nurse facilitators to support, model, and teach communication strategies that enable patients and families to secure care aligned with patients' goals over an acute episode of illness, beginning in the ICU. In a prior version of this intervention, facilitators were trained to apply communication, attachment, and mediation strategies to facilitate social cognitive components to support families. The social cognitive components were designed to: 1) build self-efficacy for communicating with clinicians; 2) improve outcome expectations that this communication can improve care; and 3) enhance behavioral capability through skill building to resolve barriers to effective communication and mediate conflict.[22] In our prior trial, the intervention reduced symptoms of depression among family members of critically ill patients with a predicted mortality of at least 30% at 6 months and reduced hospital length of stay and costs, even after accounting for intervention costs.[22–24]

Feedback from families identified limitations of our prior intervention. This feedback contributed to four specific improvements: (1) include critically ill patients with a lower severity of illness to increase proportion of eligible patients; (2) extend the intervention over 3-months, rather than restricting to the hospital stay, to enable support across transitions; (3) focus on eliciting and implementing patients' goals of care; and (4) examine factors that can impede or facilitate future implementation and dissemination using a type 1 hybrid effectiveness-implementation trial.[25]

These two trials, conducted simultaneously in the U.S. and France, have three specific aims. First, we will evaluate the effectiveness of the intervention on patient- and family-centered outcomes after critical illness. The *primary outcome* is family members' burden of symptoms of depression over the 6 months post-randomization. Second, we evaluate the intervention's effectiveness for increasing healthcare value. Finally, we use mixed-methods to understand factors and outcomes related to the implementation of this intervention. We chose to conduct two separate trials because of the dramatic differences in the healthcare cultures, the organization of healthcare systems, and the research funding mechanisms.

Methods

Overview:

We are conducting two cluster-randomized trials of a single intervention designed to improve outcomes for critically ill patients and their family. The trials are conducted in four hospitals in Seattle, Washington and four hospitals in France, including 2 hospitals in Paris ad one hospital in Brest and one in Nantes. In the US, we aim to randomize 376 patients to intervention (n=188) or control (n=188) and we estimate 564 family members (approximately 1.5 family member per patient). In France, we aim to randomize 400 patients to intervention (n=200) or control (n=200) and estimate 400 family members. US and French investigators choose slightly different numbers of patients and family members based on loss to follow-up and numbers of family members per patient from prior studies from each country.[3,22,26–30] The facilitators are experienced ICU nurses with specialized training to: 1) define and discuss goals of care with patients and families, with attention to their emotional needs; 2) support and model successful approaches for discussing goals with clinicians; 3) set expectations for success for these discussions; and 4) reduce barriers by identifying and mediating conflict. Training included at least 2 days of combined didactic and practice sessions including role play with simulated family members. A training manual will be available after study completion. Patient- and family-centered outcomes are assessed at randomization, and 1, 3, and 6 months after randomization (Figure 1).

Study population and participant eligibility

A. Patients: Using the EHR and daily ICU rounds (Monday to Friday), study staff identify consecutive patients in the ICU who meet all four of the following eligibility criteria: 1) age ≥18 years, 2) English-speaking (in the U.S.) or French-speaking (in France), 3) a family member available to participate, and 4) a chronic life-limiting illness suggesting a median survival of 2 years or a severe acute illness with a risk of hospital mortality of >15%. Chronic life-limiting illnesses, similar to our prior trial,[22] target a median survival

(without critical illness) of two years (see Appendix). Acute illness criteria include an APACHE-II (in the U.S.) or SOFA (in France) predicting a ≥15% risk of hospital mortality (the different severity of illness scores was based on tradition of prior research in each country). After initial screen and a "opt out" text page is sent to the patient's attending physician to confirm appropriateness for the study, study staff contact the patient or, if the patient doesn't have decisional capacity, a legal next of kin in-person or by phone. Decisional capacity is determined by the attending physician (or designee) to align with clinical practice.[31] Patients without decisional capacity who had no eligible family are excluded. We anticipate that the majority of eligible patients will not have decisional capacity and the intervention will focus on family participants.

C. Family: Family participants are identified by the patient if the patient has capacity. If the patient does not have decisional capacity, family are identified via the EHR or by a legal surrogate decision-maker. "Family" is not confined to immediate family. Any family or friend is eligible if they are 18 years or older and identified by the patient or legal surrogate as involved in care for the patient, provided they have primary language proficiency and no cognitive deficits limiting their ability to complete surveys. Family members are recruited by phone or in person. We do not limit the number of family members who can participate but anticipate 1–3 family members per patient.

Theoretical basis of the intervention:

This intervention draws on social cognitive theory,[18–21] which posits that the impetus for behavior change arises from interaction between people, their behaviors, and their environments. Self-efficacy, outcome expectations, and behavioral capabilities are key targets that support behavior change. Facilitators address each in our intervention:[32] 1) self-efficacy by discussing ways that patients and families have had difficult conversations in the past and what worked for them; 2) outcome expectations by discussing how having effective conversations with clinicians can help assure treatment is aligned with goals; and 3) behavioral capabilities by teaching communication skills, addressing barriers, and mediating conflict. Figure 2 shows the role of social cognitive theory within a commonly-used model for designing behavioral interventions to improve quality of life, as well as how our Aims fit in this model.[33–37]

Operationalization of intervention:

Facilitators follow each intervention patient and family for 3 months following randomization and implement the key components of the intervention summarized in Table 1. Since most eligible patients won't have decisional capacity, intervention components focus on family members.

A. Increase self-efficacy: Based on our prior research,[38–45] and the work of others,[46–51] we train facilitators to support, model, and teach family members to identify and integrate patients' values into goals of care, preferences, and decisions. Facilitators discuss times family members have navigated difficult conversations, praising successful behaviors. Activities to identify and integrate goals of care include: 1) facilitating and supporting discussions of *prognosis* among patients, families and clinicians;[52–56] 2) facilitating and

supporting discussions of *treatment preferences*;[15,46,57,58] and 3) obtaining a facilitated *values* history for incapacitated patients from family and translate this into treatment preferences.[51] Obtaining a facilitated values history includes a tool to enhance patient-centered discussions of prognosis, goals of care, and treatment preferences: the Facilitated Values History[51] for *family-clinician* communication that focuses family on the *patient's* values and goals of care. Facilitators participate in these discussions and provide guidance with this content. To increase patients' and families' capacity to define, understand and convey their goals, facilitators also elicit strong emotion and respond with empathy to allow participants to feel heard and supported. The decision psychology literature suggests that strong emotions can impair information processing and reasoning.[51] Therefore, having a facilitator elicit strong emotion with unhurried listening and empathy can help a person transition to cognitive processing and decision making.

B. Improve outcome expectations for achieving goals of care: The facilitators model and teach strategies to family members to support their expectations for having successful and effective conversations and how communicating well can improve their care. The focus on goals of care is a new addition based on feedback from the prior trial. These strategies include exploring prior experiences and the outcomes of those experiences. (Did respondents feel encouraged or discouraged? What would have helped them manage the discussion successfully? How can the facilitator help?) Additionally, using attachment theory,[59] the facilitators identify family members' interpersonal communication style to ensure that outcome expectations are appropriately tailored to each patient and family. Attachment theory provides a framework to address individuals' capacities to communicate with others and influences communication with healthcare teams.[23,60–63] Three of the 4 attachment styles pertain to about half the general population[64–66] who may derive particular benefit from the use of targeted communication skills that support difficult decision-making. For example, individuals who are predominantly "self-reliant" in stressful situations (25% of the population) may be reluctant to ask questions or participate in shared decision-making; they may benefit from being given options and feeling in charge. Those who are predominantly "support-seeking" in stressful situations (10% of the population) often have high emotional needs that may be inadequately addressed in harried healthcare settings; setting a structured schedule to have questions answered may be reassuring. Individuals with a "cautious" attachment style (10% of the population) may exhibit approach-avoidance behavior under stress so that attempts at collaborating may be abandoned out of fear of relying on others; communication that is non-judgmental and responsive can enhance trust.[63] Facilitators use a brief, valid measure of attachment styles (the Relationship Scales Questionnaire)[65] that we used successfully in our prior trial.[22] Importantly, facilitators use these styles to adapt communication approaches to meet the needs of each patient and family member.

C. Increase behavioral capability through skill acquisition and conflict mediation: Facilitators model and teach skills that support and advance successful discussions. For example, facilitators help patients and families prepare for discussions by reviewing their goals of care, writing down unanswered questions, and anticipating and planning responses to likely barriers (e.g., "clinicians are too busy", "I don't like

asking questions because I don't want to be one of those annoying people who asks too many questions"). Facilitators also model and teach ways to address conflict, a common occurrence in healthcare that frequently involves goals of care and is a key barrier to communication.[67–70] Incorporating mediation into healthcare can identify and resolve conflicts, thereby improving communication, as well as patient and family outcomes.[71–74] If patients and families feel supported and experience less conflict, they may be more able to process information and make decisions. We train facilitators in mediation principles including: summarizing the issues contributing to conflict, avoiding unwarranted assumptions that are underlying the conflict, framing issues neutrally, focusing on issues rather than personalities, and making proposals for resolution.[75–77] Facilitators model these skills for family members during the discussions about goals of care and around transitions in care settings that occur during the study period. We target all of the following types of conflict: clinician-patient, clinician-family, and intra-family.

Description of the conduct of the intervention

A. Implementation of intervention during and after the ICU: During the ICU stay, facilitators interact in person, and by phone and videoconference, with family members and many types of clinicians (physicians, nurses, social workers, etc.). Following the ICU stay, facilitators interact with patients, family and clinicians in person and by phone for 3 months from randomization (when most first readmissions occur[78–80]) or for 1 month after a patient's death occurring in the first 3 months. In-person contacts include visits to patients' homes and/or care facilities; phone contacts include calls to family members. Because prior studies suggest frequent contact is important, the schedule for contact is a minimum of every 48 hours in the ICU, every 72 hours in the acute care setting,[79,81–85] within 72 hours of change in care setting, weekly for a month after hospital discharge, and then twice monthly. The facilitators use clinical judgment if they feel more frequent contact is warranted, and family members have access to facilitators through phone and email 5 days per week. In addition to checking directly with patients/families during regular contacts (calls, visits), facilitators also access the medical record to ensure they have accurate information about appointments and treatment plans. Facilitators encourage referral to inpatient or outpatient palliative care services when they identify palliative care needs (i.e., communication, decision-making, and symptom needs). We record all facilitator contacts, including the number and type of contacts for each patient and family to assess intervention fidelity, "dose", and costs. Facilitators complete a checklist of study activities after each contact (see Appendix.)

B. Training facilitators: Training is provided by the investigators and consultants with expertise in the following areas: clinical communication skills, use of attachment theory, and mediation. Training addresses the use of these skills across care settings (e.g., inpatient, outpatient, home, care facility). Communication training includes identification of goals of care, incorporating principles of advance care planning and the facilitated values history. Attachment theory training includes understanding the four attachment styles, the consequences of these styles for communication, and the approaches most appropriate for each style. Mediation training covers skills associated with assessment and preparation: rapport building; information gathering and exchange; development and

evaluation of options; shuttle diplomacy; and resolution. Facilitators participate in role-playing exercises during training with standardized family members, and they are required to demonstrate mastery of intervention skills before engagement and during fidelity checks. We will enhance and expand our current training manual as the trial goes on, enhancing dissemination of the intervention to other institutions.

C. Intervention fidelity: To ensure scientific rigor, intervention fidelity is assessed with methods outlined by the NIH Behavioral Treatment Fidelity Workgroup on consistency in dose, providers, delivery, receipt, and enactment of interventions.[86,87] Facilitators meet weekly with investigators to discuss intervention patients and ensure intervention fidelity overall and between facilitators. Formal fidelity checks will be completed for 10% of patients/families, in which encounters are audio recorded and then compared with an intervention checklist for completion of intervention components (Appendix).

Control group:

Participants randomized to control complete the same study measures at all data collection points, but the facilitator is not involved. Contacts with study staff at all data collection points are also designed to enhance survey return rates.

Randomization:

The unit of randomization is the patient. The potential for contamination due to individual clinicians caring for patients in both groups is minimized because the focus of the intervention is specific to the individual patient and family and tailored to their needs. Randomization occurs in variable-sized blocks stratified by hospital, separately for each trial. Family members are clustered within patients. In the US and France, we allow enrollment of multiple family members per patient with no maximum. Based on prior studies, we expect 1.5 family members per patient in the US and 1.0 per patient in France.[3,22,26–30]

Outcomes and mediators:

Figure 2 shows a conceptual model for assessment of outcomes, baseline individual and environment factors, and potential mediators influencing the intervention. The outcomes and potential mediators are summarized in Table 2.

Aim 1: For Aim 1, we will evaluate the effectiveness of the intervention on one primary and several secondary outcomes. Although we will assess psychological symptoms (depression, anxiety, and PTSD) in patients and family, most critically ill patients are unable to participate. Therefore, the intervention and the outcomes focus on the family. The primary outcome is the depression subscale of the HADS over 6 months (including 1-, 3-, and 6-month assessments). These outcomes were selected based on evidence supporting their importance to patients and families.[88]

A. Depression and anxiety (with depression as the primary outcome): We assess patient and family member symptoms of depression and anxiety with the Hospital Anxiety and Depression Scale (HADS), which has become standard for ICU and post-ICU

studies.[4,88–90] The HADS is a reliable and valid 14-item, 2-domain (anxiety and depression) tool used to assess symptoms of psychological distress.[91,92] Each item is scored on a 4-point scale (ranging from 0–3) with scores for each 7 item subscale (anxiety and depression) ranging from 0–21. HADS has been used in over 700 studies with evidence of reliability, validity and responsiveness among critically ill patients and their family.[3,93–104]

B. Post-traumatic stress: We assess patient's and family's symptoms of PTSD with the Impact of Events Scale-6 (IES-6). It is derived from IES and IES-R, PTSD measures that are recommended for use with ICU survivors to evaluate PTSD[88,105,106] (Cronbach's Alpha, .80–.96 for total scores, .46–.56 for subscales; IES-R (0.96).[107,108] Each item is scored on a 4-point scale that addresses symptom severity ranging from "not at all" to "extremely", and it may be scored either as a summary score or as a mean of the 6 items.

C. Goal-concordant care: We measure concordance between the care patients want and the care they are receiving with two questions.[109] The first defines patients' goals: "If (you/the patient) had to make a choice at this time, would (you/the patient) prefer a course of treatment focused on extending life as much as possible, even if it means having more pain and discomfort, or would (you/the patient) want a plan of care focused on relieving pain and discomfort as much as possible, even if that means not living as long?" The second question assesses perceptions of current treatment using the same two options. The outcome is a dichotomous variable of whether the preference matches the report of care received. Although this creates a "false dichotomy" in that many patients want both; this "forced choice" helps identify patients' top priority.[110–112] This approach mirrors clinical practice in which goals of care are determined by the legal surrogate decision-maker when patients are unable to respond for themselves. Based on prior studies, we expect 50–60% of controls will report goal-concordant care.[109,113]

D. Quality of life: We use the QUAL-E and the QUAL-E (Fam) to assess quality of life. These companion questionnaires, one completed by patients and the other by family members, were developed systematically using focus groups, interviews and surveys to identify items, and then factor analyzed to identify quality of life domains. The QUAL-E includes 20 items in 4 domains (life completion, relationship with the healthcare system, preparation, symptom impact) with acceptable levels of fit (CFI= 0.89, GFI= 0.88, RMSEA =.06) and high levels of internal consistency (Cronbach's alpha >= 0.70 for 3 of the 4 factors). It demonstrated convergent and discriminant validity analyses against the FACIT-SP and other measures. The QUAL-E (Fam) includes 17 items in two domains (relationship with healthcare providers, completion) and additional items assessing aspects of preparedness. The QUAL-E (Fam)'s convergent and discriminant validity were supported with findings that were in line with predicted associations with the PCAS, FACIT-Sp and other measures.[114] Like other quality of life measures in which subscales assess domains that are conceptually distinct and therefore are not easily summed,[114] we selected domains and items with relevance for the current study. For the QUAL-E, these include all domains except symptom impact; for the QUAL-E (Fam), we included all 17 items.[114–116]

E. Patient and family report of self-efficacy, outcome expectations, and behavioral capacity: Participants complete the Perceived Competence Scale (PCS) as a measure of these three components derived from social cognitive theory. It is a 4-item questionnaire that has been used to measure respondent's perceptions of competency and agency at enacting the specific behaviors being assessed.[117,118] Its validity has been supported by significant associations between improved PCS scores and changes in a variety of healthcare behaviors, including short and long term tobacco cessation,[119–121] glycemic control,[118,122] and oral health.[123] Reliabilities are reported consistently at alpha > 0.80.[118,123]

Aim 2: We will examine the effectiveness of the intervention for reducing ICU and hospital readmissions and reducing costs of care. The intervention is designed to affect these outcomes by improving overall communication and, more specifically, clarifying and communicating goals of care. In France, because of universal healthcare and limited availability of cost data, this aim will focus on utilization only.

We will measure hospital readmission after initial hospital discharge through the available electronic health records (EHR), institutional billing systems, and patient/family self-reports. By using all three sources for data, we expect to capture hospitalizations that may occur outside of the healthcare system from which the patient was enrolled. Our primary focus will be readmission within 30 days of hospital discharge as this is a national standard,[124] but we will also collect hospital and ICU length of stay, emergency department visits and outpatient clinic visits from the EHR or surveys.

Aim 3: Aim 3 enables us to evaluate the factors and outcomes that influence implementation of the intervention. We will use semi-structured interviews with a purposive sample of family members, clinicians, and administrators, as well as facilitators, to identify diverse interview participants with experience with the intervention and continue recruitment until thematic saturation is achieved.

A. Key factors for implementation: Key factors that influence implementation are explored through semi-structured interviews with family members, clinicians, and administrators. Using the Consolidated Framework for Implementation Research (CFIR), questions are modified to provide a tailored assessment of the intervention and the context in which it is implemented; discussions focus on the effect of inner and outer settings, individual characteristics, and processes of care.[125]

B. Key implementation outcomes: Outcomes will be guided by the Outcomes for Implementation Research[126] and use both qualitative and quantitative measures. Qualitatively, semi-structured interviews will explore three key implementation outcomes (acceptability, fidelity, appropriateness).[126] Quantitative measures will include the proportion of eligible patients enrolled, the proportion of patients randomized to intervention who receive the intervention (facilitators talk with family members), and assessments of intervention dose (examining time spent by facilitators and intervention components delivered).

Additional measures and data

A. Description of participants: For all participants, we collect age, gender, race/ethnicity, education, employment, and social support. For patients, we collect comorbidities and severity of illness with APACHE-II (in the U.S.)[127–129] or SOFA (in France.)[130] For family, we collect relationship with the patient and whether they reside with the patient.

B. Attachment style: To identify attachment styles, we administer the Relationship Scales Questionnaire (RSQ)[65] which we successfully used as part of the prior facilitator intervention.[22]

Data collection:

Study staff involved in outcome data collection are blinded to treatment assignment.

A. Surveys: To enhance response rates, surveys may be completed in person, by phone, by mail, or online, depending on participant preference. Strategies to enhance response rates include: 1) use of study staff known to participants to contact participants at each data collection point; 2) inclusion of small monetary gratuity ($10) with each follow-up questionnaire (in the U.S. only); and 3) reminder contacts prior to, and following each distribution time point.[131,132] Families complete the same measures at the same intervals as patients with two exceptions: 1) families complete the baseline measures at randomization, while for patients there may be a delay for them to regain decisional capacity; and 2) families of patients who die receive modified surveys 4–6 weeks after a patient's death, which include the HADS, IES-6, and QUAL-E (Fam).

B. Electronic health record (EHR): We will use the EHR to supplement family report of healthcare utilization. We will also use the EHR to collect disease characteristics and specific processes of care during and after the ICU stay including treatment intensity (e.g., CPR, mechanical ventilation), transitions in care, and palliative care consults.

C. Hospital financial databases: For hospitals in the U.S., we will obtain costs associated with inpatient utilization from hospital financial databases and will link this with our EHR data.

D. Qualitative data collection: Aim 3 collects data with approximately 30 semi-structured interviews with family members (n=15), clinicians (n=10), and administrators (n=5). We use purposive sampling with the goal of a diverse group based on race/ethnicity, age, gender, and, for clinicians, specialty and year of training.

Overview of Analytic Methods

Aim 1 Analyses: Our primary outcome is family members' symptoms of depression over 6 months. We will follow the intention-to-treat principle. Our primary analysis will use a linear mixed effects model with family member symptoms at all time points (1,3, 6 months) as the response, main effects for intervention and time points, and random effects to account for multiple measurements (time points) per family member and multiple family members per patient. We will also adjust for hospital, since randomization is stratified by hospital, and

for response at randomization to improve precision. This model allows the average response to be different at 1, 3, and 6 months, but assumes the intervention has the same effect at each of these times. We will also explore whether the effect of intervention is different across time by including an interaction between time and intervention. The advantage of using the data at all 3 time points and a mixed model approach is that we can gain precision; it also allows missing responses, assuming the responses are missing at random. We will use a similar approach for the other continuous outcomes, and a generalized linear mixed effects model for the binary outcome of goal-concordant care.

Aim 2 Analyses: This aim will evaluate the effect of intervention on costs (in the U.S.) and utilization (in the U.S. and France) during the 6-month study period from the EHR, hospital financial databases and surveys. Utilization measures, including ICU-free days and hospital-free days to day 30, days in ICU, and days in hospital, will be evaluated with linear regression. As is standard for cost analyses, we plan to use generalized linear models with a gamma error distribution and identity link function, to explore the difference in mean healthcare costs for total inpatient hospital costs and disaggregated costs (direct and indirect costs), between intervention and control participants during the initial hospitalization and up to 30 days after randomization.[133] To estimate the cost of providing the intervention, we will collate study staff records of the time involved in implementing and sustaining the intervention during the trial, not including research activities such as obtaining informed consent and the evaluation of the interventions. We will then determine the average full time equivalent (FTE) over intervention patients, and convert FTE to costs based on average yearly salaries at the study sites, including benefit load. All costs will be adjusted for inflation through the study period.

Aim 3 analyses: For quantitative analyses of implementation, we will describe the proportion eligible who enroll and the fidelity with the intervention components. For qualitative analyses exploring intervention implementation, we will perform thematic analysis of transcribed interviews to explore feedback on the intervention and ways to improve the intervention delivery and implementation.[134,135] Analyses will be guided by the Consolidated Framework for Implementation Research (CFIR) in exploration of factors affecting implementation[125] and by Outcomes for Implementation Research in exploration of implementation outcomes.[126] For example, we can examine facilitators by “high” and “low” fidelity and sites by “high” and “low” penetration to examine cross-case patterns in CFIR constructs that differentiate these groups. Qualitative data will be imported into analytic software (DeDoose and NVivo), where investigators will perform iterative, inductive coding to identify recurrent themes, categories, and relationships among themes and categories. To ensure trustworthiness (a qualitative concept similar to reliability in quantitative analysis[135–138]), we will perform a “member check” of the results with prior participants selected for diversity of participant type.

Missing data: Our goal is to minimize missing data by minimizing respondent burden, offering multiple methods for survey completion, and having trained staff with repeated contact with participants. However, data could still be missing due to skipping individual

items on a survey, omissions in the EHR, lack of follow-up, or death. We will quantify the amount of missing data and apply appropriate methods to account for missing data.[139,140]

Sample size estimates

The focus for sample size estimation is the primary outcome: family member depression as assessed by the HADS depression subscale. For all calculations, we assume a two-sided test with a significance level of 0.05. If we assume 300 total family members (1 family member per patient and 150 per arm), a standard deviation of HADS depression scores of 4.2 points[141] in both arms, 3 measurements of depression (at 1, 3, and 6 months), and an intraclass correlation (ICC) of 0.2, we will be able to detect a difference in mean depression of at least 0.93 points with 80% power and 1.07 points with 90% power. If we had only 1 measurement instead of 3 per family member or, equivalently, if the ICC were 1, we would have 80% power to detect a difference of at least 1.36 points. If we have more than 1 family member per patient (1.5 is expected), we will be able to detect smaller differences at the same power. Across all of these varying conditions, detectable differences are slightly within or below the estimated minimally clinically important difference for the HADS depression scale of 1.6 to 2.0, suggesting we will have adequate power to identify a minimally clinically important difference. In the US we anticipate ≥80% complete data and in France we anticipate >75% complete data, so we aim to randomize 376 patients in the US and 400 in France to achieve at least 300 patients and at least 300 family members with complete data for each trial (U.S. and France).

Adaptations for the COVID-19 pandemic

These trials were underway when the COVID-19 pandemic started in 2020. Both trials stopped enrollment for the initial surge of COVID-19 in the US and France. Once the caseloads of COVID-19 stabilized, both trials resumed with recruitment and intervention activities occurring virtually – by phone or videoconferencing. Both trials are tracking the amount of contact occurring in person as compared to phone or videoconferencing.

Discussion

We have described two parallel randomized trials that are being conducted, one in the U.S. and one in France. These trials provide innovation and advance the science of palliative care in critical care settings in three important ways: enhancements to the intervention based on prior studies, innovation in the model of care coordination the intervention is promoting, and innovation in the use of a type 1 hybrid effectiveness-implementation trial to examine implementation processes and outcomes.[25]

This intervention is based on the intervention in a prior ICU communication facilitator study[22] and builds on prior work evaluating navigators or facilitators in a variety of settings.[142–147] However, our intervention is novel by its inclusion of nurse facilitators with innovative training that supports, models, and teaches communication skills to patients and family facing critical illness and also continues to follow patients and families beyond the ICU for three months. Since this intervention will be implemented both during and after critical illness, it addresses key gaps identified in recent systematic reviews[4,148–151] by: 1)

beginning early in the high stress time of critical illness and *following* patients after ICU; 2) focusing on communication about *goals of care*; and 3) targeting a *diverse population* (*e.g.* age, diagnoses, SES) to enhance generalizability, scalability, and cost-effectiveness.

One of the major challenges for interventions designed to improve communication about goals of care has been a limited number of validated outcomes.[152–155] We address this with standardized measures with good psychometric characteristics. The effectiveness outcomes — reducing the burden of psychological symptoms and impaired quality of life—will be assessed with well-validated measures. These measures are standard for ICU and post-ICU studies.[4,88–90] Our intervention extends over 3 months and we elected to include outcomes extending beyond the intervention to 6 months to assess whether benefit persists beyond the intervention as seen our prior study showing benefit at 6 months.[22] In addition, we assess social cognitive outcomes of behavior change (i.e., patient/family self-efficacy, outcome expectations, behavioral capacity) that are targeted by this intervention with a validated measure that will provide insights into the mechanisms that mediate the study's outcomes.[156–159]

Our primary outcome is family member symptoms of depression over the 6 months after randomization. The importance of improving outcomes for family caregivers and the value this brings to patient outcomes is well-established.[160,161] When family members suffer from the burden of critical illness, patients also suffer. Much of the suffering for family members comes from the difficulties of surrogate decision-making and the fact that most critically ill patients do not have decisional capacity.[162] Interventions that reduce family member distress also improve the care they can provide to patients.[3,22] In addition, stress extends beyond the ICU as family bear a significant burden of caregiving after the ICU.[3,93,163] As many as 20–60% of families and patients suffer a high burden of psychological symptoms during and after the ICU.[3,93,164–168] Improving communication is key because poor communication worsens distress,[169] and interventions that improve communication reduce distress.[3,22] Further, caregiver stress increases healthcare use and reduces quality of life.[170–174]

We have designed a hybrid implementation-effectiveness trial to use the innovation of implementation science to promote implementation and dissemination of effective interventions. Implementation science, or T4 translation research, is the systematic study of methods to promote the uptake and integration of health interventions.[25,126,175,176] Hybrid effectiveness-implementation trials, such as this, represent an innovative design that can facilitate more rapid translation of research into clinical practice while also evaluating the effectiveness of the intervention.[25] Improving communication in complex and diverse settings is an ideal intervention for a hybrid effectiveness-implementation trial because evidence of the value of communication is clear, but the core issue is how to efficiently implement interventions that promote effective care.[151] We are collecting data on implementation factors and outcomes in order to facilitate implementation and dissemination in the future and advance implementation science for palliative care and communication interventions.

In this paper, we have described the protocol that is being implemented in two randomized trials designed to evaluate a communication facilitator intervention to improve patient- and

family-centered outcomes for critically ill patients and their families during and after a patient's critical illness. Conducting these parallel studies in the U.S. and France provides a unique opportunity to evaluate effectiveness and implementation in two very different medical and social cultures.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Halpern NA, Pastores SM, Greenstein RJ. Critical care medicine in the United States 1985–2000: an analysis of bed numbers, use, and costs. Critical care medicine2004;32:1254–9. [PubMed: 15187502]
2. Teno JM, Gozalo P, Khandelwal N, et al.Association of Increasing Use of Mechanical Ventilation Among Nursing Home Residents With Advanced Dementia and Intensive Care Unit Beds. JAMA Intern Med2016;176:1809–16. [PubMed: 27723891]
3. Lautrette A, Darmon M, Megarbane B, et al.A communication strategy and brochure for relatives of patients dying in the ICU. N Engl J Med2007;356:469–78. [PubMed: 17267907]
4. Davidson JE, Aslakson RA, Long AC, et al.Guidelines for Family-Centered Care in the Neonatal, Pediatric, and Adult ICU. Crit Care Med2017;45:103–28. [PubMed: 27984278]
5. Long AC, Kross EK, Davydow DS, Curtis JR. Posttraumatic stress disorder among survivors of critical illness: creation of a conceptual model addressing identification, prevention, and management. Intensive Care Med2014;40:820–9. [PubMed: 24807082]
6. Davydow DS, Gifford JM, Desai SV, Bienvenu OJ, Needham DM. Depression in general intensive care unit survivors: a systematic review. Intensive Care Med2009;35:796–809. [PubMed: 19165464]
7. Pronovost PJ, Angus DC, Dorman T, Robinson KA, Dremsizov TT, Young TL. Physician staffing patterns and clinical outcomes in critically ill patients: a systematic review. JAMA2002;288:2151–62. [PubMed: 12413375]
8. Wachter RM, Goldman L. The hospitalist movement 5 years later. JAMA2002;287:487–94. [PubMed: 11798371]
9. Pantilat SZ, Alpers A, Wachter RM. A new doctor in the house: ethical issues in hospitalist systems. JAMA1999;282:171–4. [PubMed: 10411199]
10. Teno JM, Gozalo PL, Bynum JP, et al.Change in end-of-life care for Medicare beneficiaries: site of death, place of care, and health care transitions in 2000, 2005, and 2009. JAMA2013;309:470–7. [PubMed: 23385273]
11. Wolff JL, Giovannetti ER, Boyd CM, et al.Effects of guided care on family caregivers. The Gerontologist2010;50:459–70. [PubMed: 19710354]
12. Wootton R, Gramotnev H, Hailey D. Telephone-supported care coordination in an Australian veterans population: a randomized controlled trial. Journal of telemedicine and telecare2010;16:57–62. [PubMed: 20008055]
13. Amaravadi RK, Dimick JB, Pronovost PJ, Lipsett PA. ICU nurse-to-patient ratio is associated with complications and resource use after esophagectomy. Intensive Care Med2000;26:1857–62. [PubMed: 11271096]
14. Pronovost PJ, Jenckes MW, Dorman T, et al.Organizational characteristics of intensive care units related to outcomes of abdominal aortic surgery. JAMA1999;281:1310–7. [PubMed: 10208147]

15. Detering KM, Hancock AD, Reade MC, Silvester W. The impact of advance care planning on end of life care in elderly patients: randomised controlled trial. BMJ2010;340:c1345. [PubMed: 20332506]
16. Wright AA, Zhang B, Ray A, et al.Associations between end-of-life discussions, patient mental health, medical care near death, and caregiver bereavement adjustment. JAMA2008;300:1665–73. [PubMed: 18840840]
17. Botti S, Orfali K, Iyengar SS. Tragic choices: Autonmy and emotional responses to medical decisions. J Consum Res2009;36:337–52.
18. Bandura ASocial Learning Theory. New Jersey: Prentice Hall; 1977.
19. Bandura ASelf-Efficacy: Toward a unifying theory of behavior change. Psychological Reviews1977;84:191–215.
20. Bandura ASelf-efficacy mechanism in human agency. American Psychology1982;37:122–47.
21. Strecher VJ, DeVellis BE, Becker MH, Rosenstock IM. The role of self-efficacy in achieving health behavior change. Health Education Quarterly1986;13:73–91. [PubMed: 3957687]
22. 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 Med2016;193:154–62. [PubMed: 26378963]
23. Curtis JR, Ciechanowski PS, Downey L, et al.Development and evaluation of an interprofessional communication intervention to improve family outcomes in the ICU. Contemp Clin Trials2012;33:1245–54. [PubMed: 22772089]
24. Khandelwal N, Benkeser D, Coe NB, Engelberg RA, Curtis JR. Economic feasibility of staffing the intensive care unit with a communication facilitator. Ann Am Thorac Soc2016;13:2190–6. [PubMed: 27676259]
25. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care2012;50:217–26. [PubMed: 22310560]
26. Cox CE, Hough CL, Carson SS, et al.Effects of a Telephone- and Web-based Coping Skills Training Program Compared with an Education Program for Survivors of Critical Illness and Their Family Members. A Randomized Clinical Trial. Am J Respir Crit Care Med2018;197:66–78. [PubMed: 28872898]
27. Cox CE, Wysham NG, Kamal AH, et al.Usability Testing of an Electronic Patient-Reported Outcome System for Survivors of Critical Illness. Am J Crit Care2016;25:340–9. [PubMed: 27369033]
28. Cox CE, Wysham NG, Walton B, et al.Development and usability testing of a Web-based decision aid for families of patients receiving prolonged mechanical ventilation. Ann Intensive Care2015;5:6. [PubMed: 25852965]
29. Azoulay E, Pochard F, Chevret S, et al.Impact of a family information leaflet on effectiveness of information provided to family members of intensive care unit patients: a multicenter, prospective, randomized, controlled trial. Am J Respir Crit Care Med2002;165:438–42. [PubMed: 11850333]
30. Kentish-Barnes N, Chevret S, Champigneulle B, et al.Effect of a condolence letter on grief symptoms among relatives of patients who died in the ICU: a randomized clinical trial. Intensive Care Med2017;43:473–84. [PubMed: 28197680]
31. Appelbaum PS. Clinical practice. Assessment of patients' competence to consent to treatment. N Engl J Med2007;357:1834–40. [PubMed: 17978292]
32. Glanz K, Rimer BK. Theory at a Glance: A Guide for Health Promotion Practice. Bethesda, MD: National Institutes of Health, National Cancer Institute; 1997.
33. Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life: a conceptual model of patient outcomes. JAMA1995;273:59–65. [PubMed: 7996652]
34. Zubritsky C, Abbott KM, Hirschman KB, Bowles KH, Foust JB, Naylor MD. Health-related quality of life: expanding a conceptual framework to include older adults who receive long-term services and supports. Gerontologist2013;53:205–10. [PubMed: 22859435]
35. Ferrans CE. Differences in what quality-of-life instruments measure. J Natl Cancer Inst Monogr2007:22–6. [PubMed: 17951227]

36. Sousa KH, Kwok OM. Putting Wilson and Cleary to the test: analysis of a HRQOL conceptual model using structural equation modeling. Qual Life Res2006;15:725–37. [PubMed: 16688505]
37. Wyrwich K, Harnam N, Revicki DA, Locklear JC, Svedsater H, Endicott J. Assessing health-related quality of life in generalized anxiety disorder using the Quality Of Life Enjoyment and Satisfaction Questionnaire. Int Clin Psychopharmacol2009;24:289–95. [PubMed: 19707153]
38. Curtis JR, Engelberg RA, Wenrich MD, et al.Studying communication about end-of-life care during the ICU family conference: Development of a framework. J Crit Care2002;17:147–60. [PubMed: 12297990]
39. Curtis JR, Engelberg RA, Wenrich MD, Shannon SE, Treece PD, Rubenfeld GD. Missed opportunities during family conferences about end-of-life care in the intensive care unit. Am J Respir Crit Care Med2005;171:844–9. [PubMed: 15640361]
40. Curtis JR, Patrick DL, Shannon SE, Treece PD, Engelberg RA, Rubenfeld GD. The family conference as a focus to improve communication about end-of-life care in the intensive care unit: Opportunities for improvement. Crit Care Med2001;29:N26–N33. [PubMed: 11228570]
41. Curtis JR, White DB. Practical guidance for evidence-based ICU family conferences. Chest2008;134:835–43. [PubMed: 18842916]
42. White DB, Braddock CH 3rd, Bereknyei S, Curtis JR. Toward shared decision making at the end of life in intensive care units: opportunities for improvement. Arch Intern Med2007;167:461–7. [PubMed: 17353493]
43. White DB, Engelberg RA, Wenrich MD, Lo B, Curtis JR. Prognostication during physician-family discussions about limiting life support in intensive care units. Crit Care Med2007;35:442–8. [PubMed: 17205000]
44. White DB, Engelberg RA, Wenrich MD, Lo B, Curtis JR. The language of prognostication in intensive care units. Med Decis Making2010;30:76–83. [PubMed: 18753685]
45. White DB, Malvar G, Karr J, Lo B, Curtis JR. Expanding the paradigm of the physician's role in surrogate decision-making: an empirically derived framework. Crit Care Med2010;38:743–50. [PubMed: 20029347]
46. Sudore RL, Fried TR. Redefining the "planning" in advance care planning: preparing for endof-life decision making. Ann Intern Med2010;153:256–61. [PubMed: 20713793]
47. Back AL, Arnold RM, Baile WF, et al.Efficacy of communication skills training for giving bad news and discussing transitions to palliative care. Arch Intern Med2007;167:453–60. [PubMed: 17353492]
48. Back AL, Arnold RM, Tulsky JA, Baile WF, Fryer-Edwards KA. Teaching communication skills to medical oncology fellows. J Clin Oncol2003;21:2433–6. [PubMed: 12805343]
49. Walling A, Lorenz KA, Dy SM, et al.Evidence-based recommendations for information and care planning in cancer care. J Clin Oncol2008;26:3896–902. [PubMed: 18688058]
50. Weissman DE. Decision making at a time of crisis near the end of life. JAMA2004;292:1738–43. [PubMed: 15479939]
51. Scheunemann LP, Arnold RM, White DB. The facilitated values history: helping surrogates make authentic decisions for incapacitated patients with advanced illness. American journal of respiratory and critical care medicine2012;186:480–6. [PubMed: 22822020]
52. Back AL, Arnold RM. Discussing prognosis: "how much do you want to know?" talking to patients who do not want information or who are ambivalent. J Clin Oncol2006;24:4214–7. [PubMed: 16943540]
53. Fried TR, Bradley EH, O'Leary J. Prognosis communication in serious illness: perceptions of older patients, caregivers, and clinicians. J Am Geriatr Soc2003;51:1398–403. [PubMed: 14511159]
54. Hancock K, Clayton JM, Parker SM, et al.Truth-telling in discussing prognosis in advanced life-limiting illnesses: a systematic review.Palliat Med2007;21:507–17. [PubMed: 17846091]
55. Hough CL, Curtis JR. Long-term sequelae of critical illness: memories and health-related quality of life. Crit Care2005;9:145–6. [PubMed: 15774066]
56. Ehlenbach WJ, Barnato AE, Curtis JR, et al.Epidemiologic study of in-hospital cardiopulmonary resuscitation in the elderly. N Engl J Med2009;361:22–31. [PubMed: 19571280]
57. Hammes BJ. What does it take to help adults successfully plan for future medical decisions?J Palliat Med2001;4:453–6. [PubMed: 11798476]

58. Hammes BJ, Rooney BL, Gundrum JD. A comparative, retrospective, observational study of the prevalence, availability, and specificity of advance care plans in a county that implemented an advance care planning microsystem. J Am Geriatr Soc2010;58:1249–55. [PubMed: 20649688]
59. Bowlby JThe making and breaking of affectional bonds. II. Some principles of psychotherapy. The fiftieth Maudsley Lecture. Br J Psychiatry1977;130:421–31. [PubMed: 861423]
60. Ciechanowski P, Russo J, Katon W, et al.Influence of patient attachment style on self-care and outcomes in diabetes. Psychosom Med2004;66:720–8. [PubMed: 15385697]
61. Ciechanowski P, Wagner E, Schmaling K, et al.Community-integrated home-based depression treatment in older adults: a randomized controlled trial. JAMA2004;291:1569–77. [PubMed: 15069044]
62. Kaya NEffect of attachment styles of individuals discharged from an intensive care unit on intensive care experience. J Crit Care2012;27:103 e7–14.
63. Tan A, Zimmermann C, Rodin G. Interpersonal processes in palliative care: an attachment perspective on the patient-clinician relationship. Palliat Med2005;19:143–50. [PubMed: 15810754]
64. Ciechanowski PS, Katon WJ, Russo JE, Walker EA. The patient-provider relationship: attachment theory and adherence to treatment in diabetes. Am J Psychiatry2001;158:29–35. [PubMed: 11136630]
65. Griffin D, Bartholomew K. The metaphysics of measurement: The case of adult attachment. Advances in Personal Relationships1994;5:17–52.
66. Scharfe J, Bartholomew K. Reliability and stability of adult attachment patterns. Personal Relationships1994;1:23–43.
67. Breen CM, Abernethy AP, Abbott KH, Tulsky JA. Conflict associated with decisions to limit life-sustaining treatment in intensive care units. J Gen Intern Med2001;16:283–9. [PubMed: 11359545]
68. Azoulay E, Timsit JF, Sprung CL, et al.Prevalence and factors of intensive care unit conflicts: the conflicus study. Am J Respir Crit Care Med2009;180:853–60. [PubMed: 19644049]
69. Piers RD, Azoulay E, Ricou B, et al.Perceptions of appropriateness of care among European and Israeli intensive care unit nurses and physicians. JAMA : the journal of the American Medical Association2011;306:2694–703. [PubMed: 22203538]
70. Piers RD, Van den Eynde M, Steeman E, Vlerick P, Benoit DD, Van Den Noortgate NJ. End-of-life care of the geriatric patient and nurses' moral distress. J Am Med Dir Assoc2012;13:80 e7–13.
71. Dubler NN. Mediating disputes in managed care: resolving conflicts over covered services. J Health Care Law Policy2002;5:479–501. [PubMed: 15017947]
72. Dubler NN. Conflict and consensus at the end of life. Hastings Cent Rep2005;Spec No:S19–25.
73. Morreim HConflict Resolution in the Clinical Setting: A Story Beyond Bioethics Mediation. J Law Med Ethics2015;43:843–56. [PubMed: 26711422]
74. Morreim HStory of a Mediation in the Clinical Setting. J Clin Ethics2016;27:43–50. [PubMed: 27045304]
75. Gold JAdvanced Mediation Manual: Using a Faciltative Approach. Washington DC: Washington Legal Foundation; 2002.
76. Dubler NN, Liebman CB. Bioethics Mediation: A Guide to Shaping Shared Solutions. New York: United Hospital Fund; 2004.
77. Baruch Bush RA, Folger JP. The Promise of Mediation: Jossey Bass, Inc.; 1994.
78. Donze J, Aujesky D, Williams D, Schnipper JL. Potentially Avoidable 30-Day Hospital Readmissions in Medical Patients: Derivation and Validation of a Prediction Model. JAMA internal medicine2013:1–7.
79. Feltner C, Jones CD, Cene CW, et al.Transitional Care Interventions to Prevent Readmissions for Persons With Heart Failure: A Systematic Review and Meta-analysis. Ann Intern Med2014.
80. van Walraven C, Bennett C, Jennings A, Austin PC, Forster AJ. Proportion of hospital readmissions deemed avoidable: a systematic review. CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne2011;183:E391–402.

81. Brown RS, Peikes D, Peterson G, Schore J, Razafindrakoto CM. Six features of Medicare coordinated care demonstration programs that cut hospital admissions of high-risk patients. Health affairs2012;31:1156–66. [PubMed: 22665827]
82. Peikes D, Chen A, Schore J, Brown R. Effects of care coordination on hospitalization, quality of care, and health care expenditures among Medicare beneficiaries: 15 randomized trials. JAMA2009;301:603–18. [PubMed: 19211468]
83. Naylor MD, Aiken LH, Kurtzman ET, Olds DM, Hirschman KB. The care span: The importance of transitional care in achieving health reform. Health affairs2011;30:746–54. [PubMed: 21471497]
84. Naylor MD, Bowles KH, McCauley KM, et al.High-value transitional care: translation of research into practice. J Eval Clin Pract2013;19:727–33. [PubMed: 21410844]
85. Naylor MD, Brooten DA, Campbell RL, Maislin G, McCauley KM, Schwartz JS. Transitional care of older adults hospitalized with heart failure: a randomized, controlled trial. Journal of the American Geriatrics Society2004;52:675–84. [PubMed: 15086645]
86. Bellg AJ, Borrelli B, Resnick B, et al.Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. Health Psychol2004;23:443–51. [PubMed: 15367063]
87. Robb SL, Burns DS, Docherty SL, Haase JE. Ensuring treatment fidelity in a multi-site behavioral intervention study: implementing NIH Behavior Change Consortium recommendations in the SMART trial. Psychooncology2011;20:1193–201. [PubMed: 22012943]
88. Needham DM, Sepulveda KA, Dinglas VD, et al.Core Outcome Measures for Clinical Research in Acute Respiratory Failure Survivors. An International Modified Delphi Consensus Study. Am J Respir Crit Care Med2017;196:1122–30. [PubMed: 28537429]
89. Turnbull AE, Sepulveda KA, Dinglas VD, Chessare CM, Bingham CO 3rd, Needham DM. Core Domains for Clinical Research in Acute Respiratory Failure Survivors: An International Modified Delphi Consensus Study. Crit Care Med2017;45:1001–10. [PubMed: 28375853]
90. Connolly B, Hough CL. Coloring by Number? Core Outcome Measures and the Canvas of Intensive Care Unit Survivorship. Am J Respir Crit Care Med2017;196:1087–9. [PubMed: 28699762]
91. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand1983;67:361–70. [PubMed: 6880820]
92. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. J Psychosom Res2002;52:69–77. [PubMed: 11832252]
93. 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 Med2001;29:1893–7. [PubMed: 11588447]
94. 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 Med2005;171:987–94. [PubMed: 15665319]
95. Azoulay E, Pochard F, Chevret S, et al.Half the family members of intensive care unit patients do not want to share in the decision-making process: a study in 78 French intensive care units. Crit Care Med2004;32:1832–8. [PubMed: 15343009]
96. Azoulay E, Pochard F, Chevret S, et al.Meeting the needs of intensive care unit patient families: a multicenter study. Am J Respir Crit Care Med2001;163:135–9. [PubMed: 11208638]
97. Anderson WG, Arnold RM, Angus DC, Bryce CL. Posttraumatic stress and complicated grief in family members of patients in the intensive care unit. J Gen Intern Med2008;23:1871–6. [PubMed: 18780129]
98. Anderson WG, Arnold RM, Angus DC, Bryce CL. Passive decision-making preference is associated with anxiety and depression in relatives of patients in the intensive care unit. Journal of critical care2009;24:249–54. [PubMed: 19327283]
99. Fumis RR, Deheinzelin D. Family members of critically ill cancer patients: assessing the symptoms of anxiety and depression. Intensive Care Med2009;35:899–902. [PubMed: 19183953]

100. Fumis RR, Ranzani OT, Faria PP, Schettino G. Anxiety, depression, and satisfaction in close relatives of patients in an open visiting policy intensive care unit in Brazil. J Crit Care2015;30:440 e1–6.
101. Fumis RR, Ranzani OT, Martins PS, Schettino G. Emotional disorders in pairs of patients and their family members during and after ICU stay. PLoS One2015;10:e0115332. [PubMed: 25616059]
102. Garrouste-Orgeas M, Coquet I, Perier A, et al.Impact of an intensive care unit diary on psychological distress in patients and relatives*. Crit Care Med2012;40:2033–40. [PubMed: 22584757]
103. Garrouste-Orgeas M, Philippart F, Timsit JF, et al.Perceptions of a 24-hour visiting policy in the intensive care unit. Crit Care Med2008;36:30–5. [PubMed: 18090167]
104. Garrouste-Orgeas M, Willems V, Timsit JF, et al.Opinions of families, staff, and patients about family participation in care in intensive care units. J Crit Care2010;25:634–40. [PubMed: 20435430]
105. Turnbull AE, Rabiee A, Davis WE, et al.Outcome Measurement in ICU Survivorship Research From 1970 to 2013: A Scoping Review of 425 Publications. Crit Care Med2016;44:1267–77. [PubMed: 26992067]
106. Bienvenu OJ, Williams JB, Yang A, Hopkins RO, Needham DM. Posttraumatic stress disorder in survivors of acute lung injury: evaluating the Impact of Event Scale-Revised. Chest2013;144:24–31. [PubMed: 23699588]
107. Hosey MM, Bienvenu OJ, Dinglas VD, et al.The IES-R remains a core outcome measure for PTSD in critical illness survivorship research. Crit Care2019;23:362. [PubMed: 31744551]
108. Thoresen S, Tambs K, Hussain A, Heir T, Johansen VA, Bisson JI. Brief measure of posttraumatic stress reactions: impact of Event Scale-6. Soc Psychiatry Psychiatr Epidemiol2010;45:405–12. [PubMed: 19479171]
109. Teno JM, Fisher ES, Hamel MB, Coppola K, Dawson NV. Medical care inconsistent with patients' treatment goals: association with 1-year Medicare resource use and survival. J Am Geriatr Soc2002;50:496–500. [PubMed: 11943046]
110. Coast J, Huynh E, Kinghorn P, Flynn T. Complex Valuation: Applying Ideas from the Complex Intervention Framework to Valuation of a New Measure for End-of-Life Care. Pharmacoeconomics2016;34:499–508. [PubMed: 26714686]
111. Finkelstein EA, Bilger M, Flynn TN, Malhotra C. Preferences for end-of-life care among community-dwelling older adults and patients with advanced cancer: A discrete choice experiment. Health Policy2015;119:1482–9. [PubMed: 26421597]
112. Flynn TN, Bilger M, Malhotra C, Finkelstein EA. Are Efficient Designs Used in Discrete Choice Experiments Too Difficult for Some Respondents? A Case Study Eliciting Preferences for End-of-Life Care. Pharmacoeconomics2016;34:273–84. [PubMed: 26589411]
113. Curtis JR, Downey L, Back AL, et al.A patient and clinician communication-priming intervention increases patient-reported goals-of-care discussions between patients with serious illness and clinicians: a randomized trial. JAMA Intern Med2018;178:930–40. [PubMed: 29802770]
114. Steinhauser KE, Voils CI, Bosworth HB, Tulsky JA. Validation of a measure of family experience of patients with serious illness: the QUAL-E (Fam). J Pain Symptom Manage2014;48:1168–81. [PubMed: 24858740]
115. Steinhauser KE, Christakis NA, Clipp EC, McNeilly M, McIntyre LM, Tulsky JA. Factors considered important at the end of life by patients, family, physicians, and other care providers. JAMA2000;284:2476–82. [PubMed: 11074777]
116. Steinhauser KE, Clipp EC, Bosworth HB, et al.Measuring quality of life at the end of life: validation of the QUAL-E. Palliat Support Care2004;2:3–14. [PubMed: 16594230]
117. Patrick H, Williams GC. Self-determination theory: its application to health behavior and complementarity with motivational interviewing. Int J Behav Nutr Phys Act2012;9:18. [PubMed: 22385676]
118. Williams GC, Freedman ZR, Deci EL. Supporting autonomy to motivate patients with diabetes for glucose control. Diabetes Care1998;21:1644–51. [PubMed: 9773724]

119. Williams GC, Niemiec CP, Patrick H, Ryan RM, Deci EL. The importance of supporting autonomy and perceived competence in facilitating long-term tobacco abstinence. Ann Behav Med2009;37:315–24. [PubMed: 19373517]
120. Williams GC, McGregor H, Sharp D, et al.A self-determination multiple risk intervention trial to improve smokers' health. J Gen Intern Med2006;21:1288–94. [PubMed: 16995893]
121. Williams GC, McGregor HA, Sharp D, et al.Testing a self-determination theory intervention for motivating tobacco cessation: supporting autonomy and competence in a clinical trial. Health Psychol2006;25:91–101. [PubMed: 16448302]
122. Williams GC, McGregor HA, Zeldman A, Freedman ZR, Deci EL. Testing a self-determination theory process model for promoting glycemic control through diabetes self-management. Health Psychol2004;23:58–66. [PubMed: 14756604]
123. Munster Halvari AE, Halvari H, Bjornebekk G, Deci EL. Self-determined motivational predictors of increases in dental behaviors, decreases in dental plaque, and improvement in oral health: a randomized clinical trial. Health Psychol2012;31:777–88. [PubMed: 22309881]
124. Hansen LO, Young RS, Hinami K, Leung A, Williams MV. Interventions to reduce 30-day rehospitalization: a systematic review. Annals of internal medicine2011;155:520–8. [PubMed: 22007045]
125. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci2009;4:50. [PubMed: 19664226]
126. Proctor E, Silmere H, Raghavan R, et al.Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health2011;38:65–76. [PubMed: 20957426]
127. Knaus WA, Zimmerman JE, Wagner DP, Draper EA, Lawrence DE. APACHE -- Acute physiology and chronic health evaluation: A physiologically based classification system. Critical Care Medicine1981;9:591–7. [PubMed: 7261642]
128. Knaus WA, Wagner DP, Draper EA, et al.APACHE III prognostic systems: Risk prediction of hospital mortality for criticall ill hospitalized adults. Chest1991;100:1619–36. [PubMed: 1959406]
129. Kajdacsy-Balla Amaral AC, Andrade FM, Moreno R, Artigas A, Cantraine F, Vincent JL. Use of the sequential organ failure assessment score as a severity score. Intensive care medicine2005;31:243–9. [PubMed: 15668764]
130. Peres Bota D, Melot C, Lopes Ferreira F, Nguyen Ba V, Vincent JL. The Multiple Organ Dysfunction Score (MODS) versus the Sequential Organ Failure Assessment (SOFA) score in outcome prediction. Intensive care medicine2002;28:1619–24. [PubMed: 12415450]
131. Dillman DA. Mail and Internet Surveys: The Tailored Design Method. New York: John Wiley & Sons, Inc.; 2000.
132. Dotolo D, Nielsen EL, Curtis JR, Engelberg RA. Strategies for Enhancing Family Participation in Research in the ICU: Findings From a Qualitative Study. J Pain Symptom Manage2017;54:226–30 e1. [PubMed: 28438584]
133. Manning WG, Basu A, Mullahy J. Generalized modeling approaches to risk adjustment of skewed outcomes data. J Health Econ2005;24:465–88. [PubMed: 15811539]
134. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res2005;15:1277–88. [PubMed: 16204405]
135. Miles MB, Huberman AM. Qualitative Data Analysis: An expanded sourcebook. 2nd ed. Thousand Oaks, CA: Sage Publications; 1994.
136. Giacomini M, Cook DJ, for the Evidence-Based Medicine Working Group. Qualitative research in health care: Are the results of the study valid?JAMA2000;284:357–62. [PubMed: 10891968]
137. Stange KC, Miller WL, Crabtree BJ, O'Connor PJ, Zyzanski SJ. Multimethod research: Approaches for integrating qualitative and quantitative research. Journal of General Internal Medicine1994;9:278–82. [PubMed: 8046531]
138. Strauss AL, Corbin J. Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory. Thousand Oaks: Sage Publications; 1998.
139. Little R, Rubin D. Statistical analysis with missing data. Third ed. New York: Wiley; 2019.

140. Khandelwal N, Brumback LC, Halpern SD, Coe NB, Brumback B, Curtis JR. Evaluating the Economic Impact of Palliative and End-of-Life Care Interventions on Intensive Care Unit Utilization and Costs from the Hospital and Healthcare System Perspective. J Palliat Med2017;20:1314–20. [PubMed: 28972860]
141. Carson SS, Cox CE, Wallenstein S, et al.Effect of Palliative Care-Led Meetings for Families of Patients With Chronic Critical Illness: A Randomized Clinical Trial. JAMA2016;316:51–62. [PubMed: 27380343]
142. Balaban RB, Galbraith AA, Burns ME, Vialle-Valentin CE, Larochelle MR, Ross-Degnan D. A Patient Navigator Intervention to Reduce Hospital Readmissions among High-Risk Safety-Net Patients: A Randomized Controlled Trial. J Gen Intern Med2015;30:907–15. [PubMed: 25617166]
143. Chillakunnel Hussain Rawther S, Pai MS, Fernandes DJ, et al.A Randomized controlled trial to evaluate the impact of a Nurse Navigator Programme on outcomes of people with breast cancer: study protocol. J Adv Nurs2017;73:977–88. [PubMed: 27862173]
144. Green BB, Anderson ML, Wang CY, et al.Results of nurse navigator follow-up after positive colorectal cancer screening test: a randomized trial. J Am Board Fam Med2014;27:789–95. [PubMed: 25381076]
145. Percac-Lima S, Grant RW, Green AR, et al.A culturally tailored navigator program for colorectal cancer screening in a community health center: a randomized, controlled trial. J Gen Intern Med2009;24:211–7. [PubMed: 19067085]
146. Ranaghan C, Boyle K, Meehan M, Moustapha S, Fraser P, Concert C. Effectiveness of a patient navigator on patient satisfaction in adult patients in an ambulatory care setting: a systematic review. JBI Database System Rev Implement Rep2016;14:172–218.
147. Bakitas M, Lyons KD, Hegel MT, et al.Effects of a palliative care intervention on clinical outcomes in patients with advanced cancer: the Project ENABLE II randomized controlled trial. JAMA2009;302:741–9. [PubMed: 19690306]
148. Aslakson RA, Reinke LF, Cox C, Kross EK, Benzo RP, Curtis JR. Developing a Research Agenda for Integrating Palliative Care into Critical Care and Pulmonary Practice To Improve Patient and Family Outcomes. J Palliat Med2017;20:329–43. [PubMed: 28379812]
149. Aslakson R, Cheng J, Vollenweider D, Galusca D, Smith TJ, Pronovost PJ. Evidence-based palliative care in the intensive care unit: a systematic review of interventions. J Palliat Med2014;17:219–35. [PubMed: 24517300]
150. Khandelwal N, Kross EK, Engelberg RA, Coe NB, Long AC, Curtis JR. Estimating the effect of palliative care interventions and advance care planning on ICU utilization: a systematic review. Crit Care Med2015;43:1102–11. [PubMed: 25574794]
151. Tulsky JA, Beach MC, Butow PN, et al.A Research Agenda for Communication Between Health Care Professionals and Patients Living With Serious Illness. JAMA Intern Med2017;177:1361–6. [PubMed: 28672373]
152. Lo BImproving care near the end of life: Why is it so hard?JAMA1995;274:1634–6. [PubMed: 7474253]
153. Lorenz K, Lynn J. Morton SC. End-of-Life Care and Outcomes. Summary, Evidence Report/TechnologyAssessment: Number 110. AHRQ Publication Number 05-E004–1.Agency for Healthcare Research and Quality, 2004. (Accessed September 17, 2018, at https://archive.ahrq.gov/downloads/pub/evidence/pdf/eolcare/eolcare.pdf.)
154. Curtis JR, Engelberg RA. Measuring success of interventions to improve the quality of end-of-life care in the intensive care unit. Crit Care Med2006;34:S341–7. [PubMed: 17057596]
155. Patterson ES, Wears RL. Patient handoffs: standardized and reliable measurement tools remain elusive. Joint Commission journal on quality and patient safety / Joint Commission Resources2010;36:52–61.
156. Smith MS, Wallston KA, Smith CA. The development and validation of the Perceived Health Competence Scale. Health Educ Res1995;10:51–64. [PubMed: 10150421]
157. Marks GR, Lutgendorf SK. Perceived health competence and personality factors differentially predict health behaviors in older adults. Journal of Aging and Health1999;11:221–39. [PubMed: 10558436]

158. Arnold R, Ranchor AV, DeJongste MJ, et al.The relationship between self-efficacy and self-reported physical functioning in chronic obstructive pulmonary disease and chronic heart failure. Behav Med2005;31:107–15. [PubMed: 16252622]

159. Kryworuchko J, Stacey D, Bennett C, Graham ID. Appraisal of primary outcome measures used in trials of patient decision support. Patient Educ Couns2008;73:497–503. [PubMed: 18701235]

160. Adelman RD, Tmanova LL, Delgado D, Dion S, Lachs MS. Caregiver burden: a clinical review. JAMA2014;311:1052–60. [PubMed: 24618967]

161. Lynn JStrategies to ease the burden of family caregivers. JAMA2014;311:1021–2. [PubMed: 24618963]

162. Prendergast TJ, Luce JM. Increasing incidence of withholding and withdrawal of life support from the critically ill. Am J Respir Crit Care Med1997;155:15–20. [PubMed: 9001282]

163. Siegel MD, Hayes E, Vanderwerker LC, Loseth DB, Prigerson HG. Psychiatric illness in the next of kin of patients who die in the intensive care unit. Crit Care Med2008;36:1722–8. [PubMed: 18520637]

164. Desbiens NA, Mueller-Rizner N, Connors AF Jr., Wenger NS, Lynn JThe symptom burden of seriously ill hospitalized patients. SUPPORT Investigators. Study to Understand Prognoses and Preferences for Outcome and Risks of Treatment. J Pain Symptom Manage1999;17:248–55. [PubMed: 10203877]

165. Jones C, Skirrow P, Griffiths RD, et al.Post-traumatic stress disorder-related symptoms in relatives of patients following intensive care. Intensive Care Med2004;30:456–60. [PubMed: 14767589]

166. Kross EK, Curtis JR. Burden of psychological symptoms and illness in family of critically ill patients: what is the relevance for critical care clinicians?Crit Care Med2008;36:1955–6. [PubMed: 18520648]

167. Needham DM, Davidson J, Cohen H, et al.Improving long-term outcomes after discharge from intensive care unit: report from a stakeholders' conference. Critical care medicine2012;40:502–9. [PubMed: 21946660]

168. Davidson JE, Jones C, Bienvenu OJ. Family response to critical illness: postintensive care syndrome-family. Critical care medicine2012;40:618–24. [PubMed: 22080636]

169. Tilden VP, Tolle SW, Garland MJ, Nelson CA. Decisions about life-sustaining treatment: Impact of physicians' behaviors on the family. Arch Intern Med1995;155:633–8. [PubMed: 7887760]

170. Sharpe M, Burton C, Sawhney A, McGorm K, Weller D. Is co-morbid depression adequately treated in patients repeatedly referred to specialist medical services with symptoms of a medical condition?Journal of psychosomatic research2012;72:419–21. [PubMed: 22656436]

171. Luppa M, Sikorski C, Motzek T, Konnopka A, Konig HH, Riedel-Heller SG. Health Service Utilization and Costs of Depressive Symptoms in Late Life - A Systematic Review. Current pharmaceutical design2012;18:5936–57. [PubMed: 22681171]

172. Schillerstrom JE, Royall DR, Palmer RF. Depression, disability and intermediate pathways: a review of longitudinal studies in elders. Journal of geriatric psychiatry and neurology2008;21:183–97. [PubMed: 18838741]

173. McKnight PE, Kashdan TB. The importance of functional impairment to mental health outcomes: a case for reassessing our goals in depression treatment research. Clinical psychology review2009;29:243–59. [PubMed: 19269076]

174. Visser MR, Smets EM. Fatigue, depression and quality of life in cancer patients: how are they related?Support Care Cancer1998;6:101–8. [PubMed: 9540167]

175. Peters DH, Adam T, Alonge O, Agyepong IA, Tran N. Implementation research: what it is and how to do it. BMJ2013;347:f6753. [PubMed: 24259324]

176. Bauer MS, Damschroder L, Hagedorn H, Smith J, Kilbourne AM. An introduction to implementation science for the non-specialist. BMC Psychol2015;3:32. [PubMed: 26376626]

177. Ciechanowski PS, Russo JE, Katon WJ, et al.The association of patient relationship style and outcomes in collaborative care treatment for depression in patients with diabetes. Med Care2006;44:283–91. [PubMed: 16501401]

178. Ciechanowski PS, Walker EA, Katon WJ, Russo JE. Attachment theory: a model for health care utilization and somatization. Psychosom Med2002;64:660–7. [PubMed: 12140356]

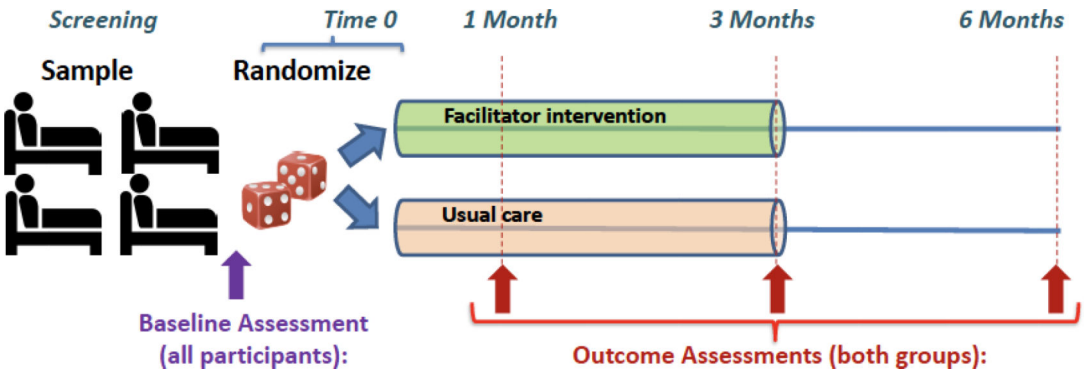

Figure 1:
Overview of the study timeline

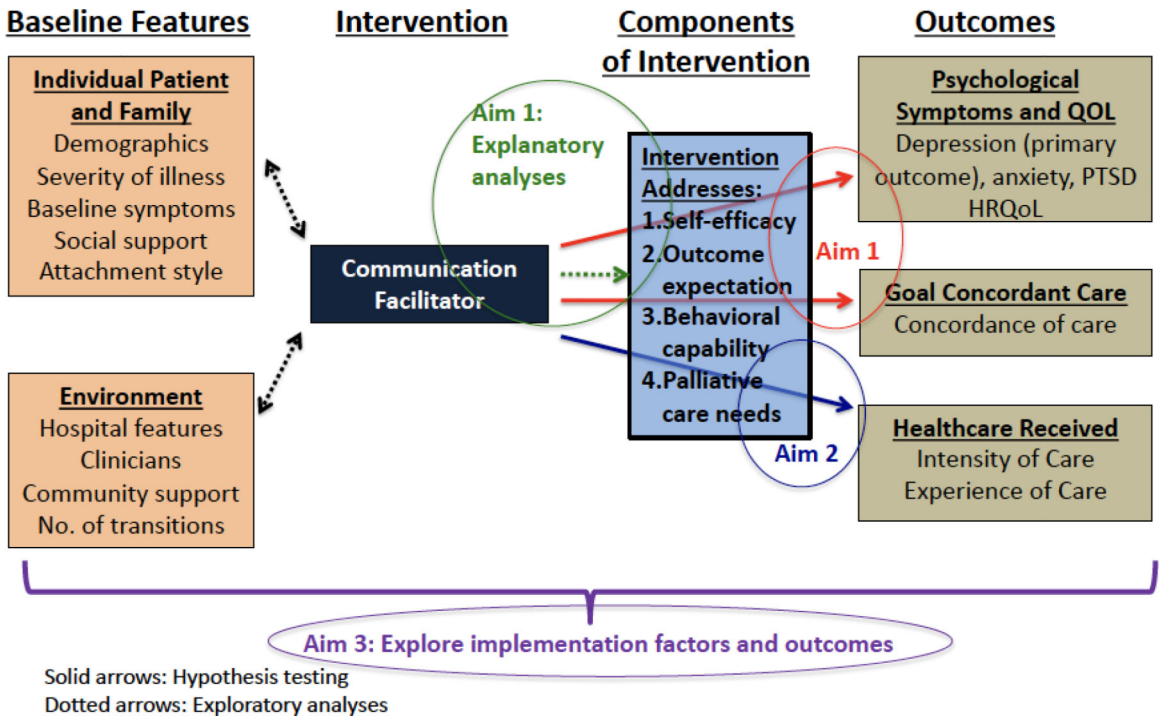

Figure 2:
Conceptual Model for study

Table 1:

Overview of the Key Components of the Intervention

GOALS	FACILITATOR SKILLS OR TASKS	TOOLS
A. Increase self-efficacy for identifying and discussing goalsof-care	Support discussions of prognosis and of values, goals and preferences	Facilitated values history[51]
B. Improve outcome expectations by identifying and resolving barriers	Discuss how effective communication can alter and improve treatment plans	Attachment theory to adapt communication[177,178]
C. Increase behavioral capacity with skills in communication & mediation	Address barriers; identify and mediate conflict; teach mediation skill	Mediation training for facilitators[73,74]

Table 2:

Main study measures and data collection protocol

MAIN OUTCOME MEASURES	CONCEPT	DATA COLLECTION: SOURCE & TIME
Aim 1: Outcomes		
Primary Outcome: HADS depression score	Depressive and anxiety symptoms	**Patients and/or Families:** Enrollment (if able),1, 3, 6, months post-randomization for all; 1 month after death for family members
SUPPORT question[109]	Goal-concordant care	
Impact of event scale (IES)[88,105,106]	Post-traumatic stress symptoms	
QUAL-E and QUAL-E (Fam)[114–116]	Quality of life	
Aim 1: Potential Mediators of the Intervention		
Perceived Competence Scale (PCS)[117,118]	Efficacy/capability/ expectations for health behavior	**Patients and/or Families:** Enrollment (if able),1, 3, 6 months post-randomization
Aim 2: Outcomes		
Hospitalizations, ICU admits,, palliative care consultations	Healthcare utilization; use of palliative care	**Medical record:** After-death or 6 months
Hospital and ICU costs	Inpatient costs of care from index hospitalization (direct and indirect)	**Medical record/financial databases**(US only)
Aim 3: Implementation Factors and Outcomes		
Domains: intervention, settings, individual, process	Key factors identified from CFIR[125]	**Patients/families/clinicians:** Qualitative interviews
Outcomes: acceptability, fidelity, penetration	Key outcomes identified by Proctor[126]	