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ORIGINAL

A randomised controlled trial of a nurse facilitator to promote communication for family members of critically ill patients

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Abstract

Purpose: Suboptimal communication with clinicians, fragmented care and failure to align with patients' preferences are determinants of post intensive care unit (ICU) burden in family members. Our aim was to evaluate the impact of a nurse facilitator on family psychological burden.

Methods: We carried out a randomised controlled trial in five ICUs in France comparing standard communication by ICU clinicians to additional communication and support by nurse facilitators. We included patients > 18 years, with expected ICU length of stay > 2 days, chronic life-limiting illness, and their family members. Facilitators were trained to help families to secure care in line with patient's goals, beginning in ICU and continuing for 3 months. Assessments were made at baseline and 1, 3 and 6 months post-randomisation. Primary outcome was the evolution of family symptoms of depression over 6 months using a linear mixed effects model on the depression subscale of the Hospital Anxiety and Depression Scale (HADS). Secondary outcomes included HADS-Anxiety, Impact of Event Scale-6, goal-concordant care and experience of serious illness (QUAL-E).

Results: 385 patients and family members were enrolled. Follow-up at 1-, 3- and 6-month was completed by 284 (74%), 264 (68.6%) and 260 (67.5%) family members respectively. The intervention was associated with significantly more formal meetings between the ICU team and the family (1 [1–3] vs 2 [1–4]; $p < 0.001$). There was no significant difference between the intervention and control groups in evolution of symptoms of depression over 6 months ($p = 0.91$), nor in symptoms of depression at 6 months [0.53 95% CI (− 0.48; 1.55)]. There were no significant differences in secondary outcomes.

Conclusion: This study does not support the use of facilitators for family members of ICU patients.

Keywords: Intensive care, Nurse facilitator, Family members, Communication, Post-ICU burden

Introduction

Admission to the intensive care unit (ICU) can be a challenging experience for patients and their families. Indeed, during and after the ICU stay, they may suffer from psychological burden, including symptoms of anxiety, depression and posttraumatic stress [1–4]. They may also experience unsatisfactory and ineffective

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communication [4, 5], as well as fragmented care due to the numerous transitions across clinicians and settings [6]. In the absence of continuity, 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. Key communication problems include being unable to articulate goals of care; not having skills, confidence, and beliefs that communicating with multiple clinicians can lead to better outcomes; and being too distressed to process information to make informed choices that are goal-concordant [7]. Finally, and more specifically, family satisfaction with care is strongly influenced by hospital culture, with the most important feature of this culture being management of transitions at the end of the ICU stay [8]. Therefore, critically ill patients and their families are important targets for interventions to improve communication across transitions. Outside the ICU setting, prior studies including interventions such as patient navigation, discharge planning, or care coordination have shown some reductions in re-hospitalizations [9], but few have had a significant effect on psychological distress. Improving communication helps reduce psychological burden in family members [10, 11] and may improve goal-concordant care. Previous research also stresses the importance of interventions well integrated within the ICU team [12].

Building on social cognitive theory [13] and prior work [14], we co-designed with J. Randall Curtis 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. This study is part of a joint project between France and the United States (US) [15].

Take-home message

An intensive care unit nurse facilitator 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 is not associated with a decrease of depression symptoms in families nor with an increase of goal concordant care.

Methods

Study design

From February 5, 2020 to January 21, 2023, this randomised controlled clinical trial was conducted in five university hospitals in France. ICU characteristics are detailed in supplemental Table 1. The study protocol was approved by the Comités de protection des personnes (CPP) Ile de France V (18/08/2019, ref 70728). The protocol and statistical analysis plan were published [15]. The study was registered on ClinicalTrial.gov on 21/10/2019 and the first patient was enrolled on 05/02/2020. Initially we obtained written informed consent or deferred consent (when lacking decisional capacity) from patients and written informed consent from family members before study inclusion and randomisation. Due to the coronavirus disease 2019 (COVID-19) pandemic, the study was interrupted between 22/03/2020 and 01/09/2020. From 03/12/2020, the institutional review board authorised oral consent from patients and family members due to the pandemic.

Participants

Patient inclusion criteria were age 18 years or older, admitted to the ICU with an expected length of stay of at least 2 days, a chronic life-limiting illness suggesting a median survival of approximately 2 years or a risk of hospital mortality of > 15% using Sequential Organ Failure Assessment (SOFA) score, French speaking, with visiting relatives, and informed or deferred consent (when lacking decisional capacity). Family inclusion criteria were age 18 years or older, French speaking, identified as the legal surrogate decision-maker and who provided informed consent.

Randomisation

The unit of randomisation was the patient. The potential for contamination was minimised because the focus of the intervention was specific to the individual patient and family and tailored to their needs. Randomisation occurred in variable-sized blocks (blocks of either 2 or 4, unknown from the investigators) stratified by site. Randomisation occurred after patient and/or family consent to participate in the study. Randomisation of patients was centralised and carried out using a computerised system in the electronic case research form (eCRF) website (Cleanweb, https://tentelemed.com/clinical-research/) according to a predefined randomisation list. Distribution in the two groups was made in a 1:1 ratio (1:1 matching between patient and family member).

Procedures

Intervention group

Training facilitators

A 2-day training session was provided by the investigators and external consultants with expertise in clinical communication skills, use of attachment theory, and mediation. Communication training included improving overall communication, as well as identification of goals of care, incorporating principles of advance care planning and the facilitated values history. Mediation training covered skills associated with rapport building; information gathering and exchange; development and evaluation of

options; and resolution. Facilitators participated in role-playing exercises during training with standardised family members, and they were required to demonstrate mastery of intervention skills before engagement and during fidelity checks. After interruption of the study due to the COVID-19 pandemic, a second day-and-a-half session was organised to update the facilitators' communication skills.

Implementation of the intervention

The facilitator was expected to support, serve as a role model for, and teach families in identifying and effectively communicating patients' goals of care with clinicians. Social cognition theory, which incorporates self-efficacy, outcome expectations, and behavioural skills as essential components of behaviour change, served as the theoretical foundation for the development of the intervention. Facilitators' roles were (1) to improve families' feeling of self-efficacy to communicate with clinicians in a variety of settings; (2) to reflect on the impacts of communication on quality of care (by exploring prior experiences and the outcomes of those experiences); and (3) to address behavioural capability through skill building to resolve barriers to effective communication and mediate conflict. In practical terms, the facilitators' role was to help families prepare for interviews with the doctor in charge of the patient: what information did they want to share, what questions did they want to ask, what difficulties were they experiencing, what were their specific needs—and once these were identified, the facilitator would strive to help families express these questions/difficulties/needs. The idea was to encourage self-efficacy and not to replace direct contact between the team and the family. Their role was also to accompany families during meetings and then debrief these meetings, on the one hand with the family and on the other with the doctor and nurse who were present. Facilitators shared any relevant information with the team and re-explained information to families. Last, their role was also to provide support and practical advice to family members.

The intervention started within 24 h of ICU admission. Throughout the ICU stay, facilitators interacted in person, by phone and videoconferences, with family members as well as with different types of clinicians (physicians, nurses, social workers, etc.). After ICU discharge, facilitators interacted with patients, family and clinicians in person and by phone for 3 months from randomisation or for 1 month after a patient's death occurring in the first 3 months. In-person contacts included meeting the patient and the family in the hospital; phone contacts included calls to family members and patients, as well as text messages. Because prior studies suggest frequent contact is important, the schedule for contact was a minimum of every 48 h in the ICU, every 72 h in the acute care setting, within 72 h of change in care setting, weekly for a month after hospital discharge, and then twice monthly. The facilitators used clinical judgement if they felt more or less frequent contact was warranted and family members had access to facilitators through phone and email five days per week. In addition to checking directly with patients/families during regular contacts (calls, visits), facilitators also accessed the medical record to ensure they had accurate information about appointments and treatment plans. We recorded all facilitator contacts, including the number and type of contacts for each patient and family to assess intervention fidelity. Facilitators completed a checklist of study activities after each contact (supplemental Table 2).

Control group

Patients randomised to the control group received standard of care by the ICU team, with no implication of the facilitator. Usual care in the participating ICUs can be summarised as: open visitation policies (excluding pandemic period); a routine multidisciplinary meeting at day 3 to review the patient's situation (diagnosis, treatment, prognosis), followed by meetings when deemed necessary by the doctor or the family; the possibility for families to meet with a psychologist and/or a social worker.

Outcomes

Primary outcome

The primary outcome was family symptoms of depression over 6 months captured using the Hospital Anxiety and Depression Scale (HADS) completed at baseline, 1-, 3- and 6 months. The HADS is a reliable and valid 14-item, 2-domain (anxiety and depression) tool used to assess symptoms of psychological distress [16]. Each item is scored on a 4-point scale (ranging from 0 to 3) with scores for each 7-item subscale (anxiety and depression) ranging from 0 to 21. HADS has been used in over 700 studies with evidence of reliability, validity and responsiveness among critically ill patients and their family. The primary endpoint is family symptoms of depression over 6 months.

Secondary outcomes

Anxiety

We assessed family's symptoms of anxiety using the HADS anxiety subscale (see above).

Post-traumatic stress

We assessed family's symptoms of post-traumatic stress disorder (PTSD) at 1-, 3- and 6 months with the Impact of Events Scale-6 (IES-6) derived from IES and IES-R [17]. Each item is scored on a 4-point scale that addresses

symptom severity from "not at all" to "extremely", ranging from 0 to 24. The IES-6 was completed at 1-, 3- and 6 months.

Goal-concordant care

We measured concordance between what care the family believed the patients would want and the care they were receiving with two questions [18]. The first defines patients' goals: "If the patient had to make a choice at this time, would the patient prefer a course of treatment focussed on extending life as much as possible, even if it means having more pain and discomfort, or would the patient want a plan of care focussed 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 [19]. 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.

Quality of life

We used the QUAL-E (Fam) to assess quality of life that includes 17 items in three domains (relationship with healthcare providers, completion and preparedness), resulting in three composite scores [20], calculated by the sums of corresponding items.

The data in the tables and figures were collected prospectively using an electronic case report form.

Data collection

All telephone follow-up interviews were blinded and were conducted by trained psychologists from our research group. Strategies to enhance response rates included: (1) follow-up research calls done by the same person to allow for continuity; (2) reminder contacts prior to, and following each distribution time point. We used the electronic health record (EHR) to collect disease characteristics and specific processes of care during and after the ICU stay, including treatment intensity (e.g. cardiopulmonary resuscitation, mechanical ventilation), transitions in care, and palliative care consults.

Statistical analysis

Sample size

The primary focus for sample size estimation was the primary outcome and was based on the mean family member depression over 6 months as assessed by the HADS depression subscale. For all calculations, we assumed 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 in both arms, 3 measurements of depression (at 1, 3, and 6 months), and an intraclass correlation (ICC) of 0.2, we would have been able to detect a difference in mean depression of at least 1.07 points with 90% power. We anticipated > 75% complete data for all outcomes so we planned to randomize 400 patients to achieve at least 300 family members with complete data.

Our primary outcome was family members' symptoms of depression over 6 months. We followed the intention-to-treat principle. Continuous variables are summarised as medians and interquartile ranges (IQRs) and categorical variables as counts and percentages. Implementation of the intervention was assessed using checklists and the number of facilitator contacts over time in the intervention group. Our primary analysis used a linear mixed effects model with family member symptoms at all time points (baseline, 1, 3, and 6 months) as the response with a main effect for time and an interaction time/intervention. The intervention effect was assessed by testing to 0 the interaction time/intervention using a Wald test. A random effect on intercept was added to account for multiple measurements (time points) per family member. We also adjusted for hospital, since randomisation is stratified by hospital. This model allows the average response to be different at 1, 3, and 6 months, but assumes the effect of the intervention on the time effect is the same over time. The advantage of using the data at all three time points and a mixed model approach is that we gain precision; it also allows missing responses, assuming the responses are missing at random conditionally on time and hospital. We used a similar approach for the other continuous outcomes and binary outcomes, using linear mixed effect models or logistic mixed effect models respectively. Mean differences between groups for continuous outcomes and their 95% confidence interval (CI) are given at each time point. Proportion differences between groups for binary outcomes and their 95% CI are given at each time point. A sensitivity analysis was performed as initially planned in the protocol (per-protocol primary analysis), using a different random effect linear model: only family member symptoms at 1, 3, and 6 months were considered as the response. Main effects for intervention and time points were adjusted for hospital and for response at randomisation. 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. In this analysis, the intervention effect is directly tested using a Wald test. A second sensitivity analysis was performed to evaluate the robustness of

results by using a multiple imputation by chained equations (MICE) to handle missing data [21]. Forty imputed datasets were generated with a MICE algorithm of 10 iterations.

Statistical tests were not adjusted for multiple comparisons. Because of the potential for type I error due to multiple comparisons, the findings for analyses of secondary end points should be interpreted as exploratory. All reported p values are 2-sided; a p value of less than 0.05 was considered statistically significant. All analyses were performed using R version 4.3.1 (http://www.R-project.org/).

Results

Between Feb 5, 2020, and March 31, 2022, 5148 consecutive patients were admitted in the five participating ICUs. The study eligibility criteria were met by 1130 patients and relatives, and 404 relatives were included in the trial (202 in the control and 202 in the intervention arm). 1-, 3- and 6-month follow-up interviews were completed by 284 (74%), 264 (68.6%) and 260 (67.5%) family members respectively (Fig. 1). There were no significant differences in patient and family characteristics between those who completed follow-up and those who were lost to follow-up (supplemental Table 3).

Table 1 describes the main characteristics of the patients and family members as well experience in the ICU. ICU length of stay was no different between the two groups. Table 2 shows that facilitators implemented the intervention more often during the ICU stay than after. Supplemental Fig. 1 confirms this trend, showing that interventions occurred most often within 20 days from study inclusion. Goals of care were addressed in 89% of situations in the ICU. The facilitators adapted support depending on families' specific needs (mediation, self-efficacy), both during the ICU stay and after. The least addressed concerns were financial and spiritual preoccupations as well as end of life discussions. Table 2 also shows that the number of formal meetings between the family and the ICU team was significantly higher in the intervention (1 [1–3] in the control group vs 2 [1–4] in the intervention group (median IQR); $p < 0.001$).

There was no significant difference between the intervention and the control group in evolution of symptoms of depression over 6 months ($p = 0.91$), nor in symptoms of depression at 6 months [0.53 (−0.48; 1.55)] (Table 3; Fig. 2). Secondary outcomes show no difference between the two groups. Indeed global HADS score, anxiety sub-score, IES-6 score and SF-1 score (short version of the functional health status scale) were similar in both groups, showing no effect of the intervention on psychological burden. Similarly, concordance between what care the family believed the patient would want and the care the patient received was low at all three time-points and no different between the two groups.

Sensitivity analyses did not report different results, except for the primary endpoint which suggested that family members from the intervention group presented with a higher prevalence of symptoms of depression over the 6 months that followed randomisation (supplemental Table 4). Moreover, the results were similar for the primary endpoint after applying multiple imputation.

Discussion

In this randomised controlled trial, we assessed the impact of a nurse facilitator in 385 patients facing chronic life-limiting illnesses or at high risk of death. The study did not show decrease in symptoms of depression over time, or of any of the secondary outcomes, such as symptoms of anxiety and post-traumatic stress or impact on goal concordant care.

A nurse facilitator is a feasible intervention and qualitative research has emphasised that ICU clinicians perceive the nurse facilitator as an effective way to enhance communication and support for both families and clinicians [22]. It has also been found to be a cost-effective intervention [23]. A previous randomised controlled trial suggested that the intervention could reduce the proportion of family members with symptoms of depression [14]. However, a similar larger scale evaluation failed to demonstrate any benefit on family mental health symptoms [24]. That the PARTNER trial and the current trial both failed to produce significant improvements in mental health outcomes resonates with prior research, exemplified by the groundbreaking work of the SUPPORT investigators [25]. Although frequent and severe, symptoms of anxiety, depression and PTSD are mostly associated with non-modifiable factors [1], making preventive strategies extremely challenging [12, 14, 26, 27]. Studies that reported a reduction in mental health outcomes all included patients at the time of death [10, 11, 14]. Future trials to improve goals of care discussions with the critically ill and their family members should include patients at higher risk of death, and use focussed interventions specifically targeting the modifiable determinants of psychological burden.

In the PARTNER trial [24], while family burden was not decreased, results offered a compelling perspective on a family-support intervention delivered by ICU nurses trained to enhance clinician–family communication, a major unmet need [28]. Indeed, quality of communication, Perception of Patient Centeredness, and length of ICU stay among patients who died were significantly improved by the intervention. This suggests that interventions targeting communication might still result in substantial benefits. Moreover, as not only one but four

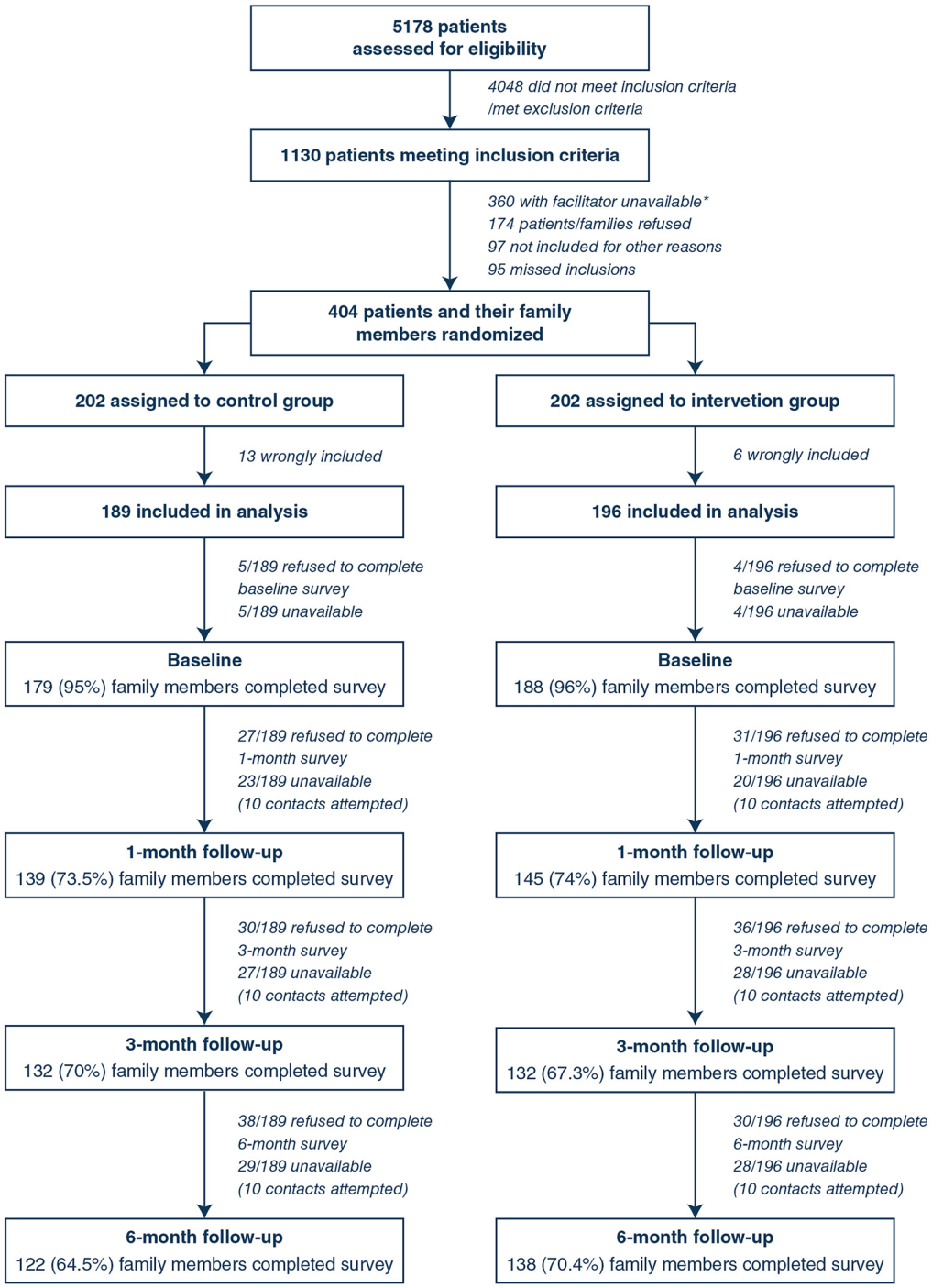

Fig. 1 CONSORT flow diagram. *Unavailable: facilitator away (vacation, health issues) or work overload

to six nurses at each ICU were trained to deliver and oversee the intervention, continuity might have been more sustained in the PARTNER trial.

In the present trial, facilitator's training also focussed on improving discussions about goals of care, rather than only enhancing overall communication in the ICU, although this had no impact on perceived concordance—concordance being particularly low in both groups. Our results show that while facilitators indeed offered comprehensive support, their influence on decision-making

Table 1 Patients', family members' and ICU experience characteristics

	Control group without facilitator	Intervention group with facilitator
Patients' characteristics		
	N = 189	*N* = 196
Age	63.4 [52.9; 70.8]	65.1 [55.6; 71.8]
Female gender	141 (74.6%)	138 (70.4%)
One or more hospitalizations prior to ICU admission	82 (46·6%)	94 (49%)
NA = 17	NA = 13	NA = 4
Cause of ICU admission		
Shock	26 (13.8%)	34 (17.3%)
Sepsis	25 (13.2%)	20 (10.2%)
Cardiopulmonary arrest	23 (12.2%)	13 (6.6%)
Acute respiratory failure	71 (37.6%)	83 (42.3%)
Neurological	21 (11.1%)	23 (11.7%)
Haematological	15 (7.9%)	21 (10.7%)
Charlson Comorbidity Index	3 [2; 4]	3 [2; 5]
During ICU stay		
Mechanical ventilation	152 (80.4%)	160 (81.6%)
Non-invasive ventilation	43 (23.8%)	49 (25%)
High-flow oxygen ventilation (Optiflow)	72 (39.8%)	68 (34.7%)
Cardiopulmonary resuscitation	10 (5.4%)	8 (4.1%)
Dialysis	52 (28.6%)	57 (29.1%)
Surgical intervention	45 (24.6%)	36 (18.4%)
Palliative comfort care documented in the medical record	22 (12%)	20 (10.2%)
Length of ICU stay (days)	12 [7; 33]	14 [7; 32]
Place of transfer after ICU discharge		
Hospital ward	106 (77.4%)	118 (81.9%)
Other hospital or health facility	28 (20.4%)	24 (16.7%)
Home hospitalisation	0 (0%)	1 (0·7%)
Home	1 (0.7%)	0 (0%)
Other	2 (1.5%)	1 (0.7%)
NA = 94	NA = 52	NA = 42
ICU mortality	48 (25.8%)	52 (26.5%)
Decisions made in the ICU		
DNR order	9 (4.9%)	22 (11.3%)
Decision to withhold treatment	86 (22.3%)	43 (21.9%)
Decision to withdraw treatment	19 (10.3%)	22 (11.2%)
Survival (IC 95%)		
1 month	68.1% (61.6–75.3%)	68.8% (62.6–75.6%)
3 months	61.9% (55.1–69.6%)	59.1% (52.4–66.5%)
6 months	57.8% (50.8–65.8%)	56.5% (49.7–64.1%)
Family members' characteristics		
Age	52.7 [41.6; 62.5]	56.3 [44.6; 65.3]
Female gender	127 (67.2%)	149 (76%)
Education (highest diploma)		
No high school diploma	22 (12.3%)	14 (7.5%)
High school diploma	79 (40.2%)	82 (43.4%)
Associate degree or certificate	24 (13.4%)	27 (14.5%)
Bachelor's degree	26 (14.5%)	27 (14.5%)
Master's degree and over	35 (19.6%)	36 (19.4%)

Table 1 (continued)

	Control group without facilitator	Intervention group with facilitator
NA = 20	NA = 10	NA = 10
Professional activity		
Full time	90 (50.8%)	83 (43.9%)
Part time	12 (6.8%)	12 (6.3%)
No professional activity	11 (6.2%)	11 (5.8%)
Disability that prevents from working	1 (0.6%)	2 (1.1%)
Retired	45 (25.4%)	59 (31.2%)
Other	18 (10.2%)	22 (11.6%)
NA = 19	NA = 12	NA = 7
Change in professional status due to patient's health-between baseline and month 6	41 (26.6%)	46 (27.9%)
NA = 66	NA = 35	NA = 31
Relationship to the patient		
Spouse/partner	79 (41.8%)	106 (54.1%)
Brother/sister	22 (11.6%)	10 (5.1%)
Parent	15 (7.9%)	17 (8.7%)
Adult child	62 (32.8%)	56 (28.6%)
Other	13 (7%)	10 (5%)

processes remained relatively limited. This delineates a scenario wherein the facilitator's role potentially encompassed emotional and informational assistance more than direct influence on care goals of care. Also, as only one in four patients died in the ICU, the goals of care discussions might have felt inappropriate or offbeat for the majority of included family members. The present trial, while lacking in measurable improvement in primary and secondary endpoints, leaves room for the hypothesis that our intervention's influence might have extended beyond the purview of our measurement instruments or would have led to different results in a population of sickest ICU patients, in whom goals of care discussions would have been more timely.

The novelty of the present intervention was also the prolongation of the facilitator's role after ICU discharge as critically ill patients and their families are particularly vulnerable to transitions not only in clinicians, but also in the location of their care with the disruptions in communication and coordination of care that accompany them. However, this prolonged support does not show improvement in family well-being, or in goal concordance care. Although support is needed during transitions in care trajectory, this follow-up by an ICU facilitator may have led to a feeling of continuous connection to the ICU environment and the difficulty to move forward, showing how challenging designing support strategies can be.

This study has several limitations. First, it was performed in France, where ICU facilitators and navigators have never been part of ICU teams before this trial, with potential challenges in anticipating this new role within the teams. Novelty of the facilitator role may have made the intervention difficult to implement both for facilitators (discovering new roles and new forms of interactions) and for the ICU teams (systematic involvement of the facilitator, accepting the intervention of "new clinicians", etc.) as well as for post-ICU clinical teams less aware of the nature of the intervention. The experimental nature of the study in France may have been underestimated when it was launched. Moreover, health coverage, family interactions and decision making might differ compared to other countries [29], as well as approaches to discussions about goals of care, financial stress and spiritual care, including nurses' roles in these discussions [30]. However, this trial was also done in the US and comparison between the two trials will be informative. Second, one third of family members were lost to follow-up at 6 months—however, this is common in follow-up studies. Third, training may have been insufficient for nurses unaccustomed to discuss complex issues with family members, such as goals of care. Fourth, the unprecedented COVID-19 pandemic necessitated adaptations, potentially affecting the delivery of the intervention and altering its focus from goal concordance to continuity of information and support. The pandemic caused restrictions on family visits and intensified psychological burden. This potentially intertwined with our intervention's effects, contributing to outcomes in manners that prove challenging to

Table 2 Implementation of the intervention by facilitators

	During ICU stay	During hospital stay	Post-hospital stay
A. Description of the 3 components of facilitators' intervention[a,b]			
1. Communication and goals of care			
Overall, goals of care discussed	89%	86.2%	73.8%
Overall, family's preoccupations addressed	82.6%	75.3%	66.2%
Depending on context and patient's health			
End of life decision-making addressed	3%	1%	0.4%
Short term organisation addressed	46.7%	37%	23.4%
Long term organisation addressed	7.5%	8.1%	6.3%
Family implication in meetings with ICU team	19.9%	9.3%	2.5%
Patient's transfer discussed	16.6%	37%	11.1%
Change in care discussed	5.6%	6.2%	2.3%
Death and bereavement discussed	7.5%	4.8%	3.2%
Communication issues with the team discussed	31.1%	29.2%	7.5%
Financial concerns discussed	4.2%	2.4%	2.9%
Values discussed depending on context and patient's health			
Related to physical concerns (autonomy etc.)	26.2%	23%	21.1%
Related to emotional concerns (what is most important for the patient)	32%	29.6%	22.1%
Related to spiritual concerns	6%	1.5%	1.2%
2. Tensions/conflict/mediation			
Overall, tensions/conflict were addressed	11.5%	12.1%	10.1%
Identification of tensions	10.4%	10.5%	8.6%
Easing of tension/resolution	5.1%	6.6%	8.6%
Practical problems discussed	2%	1.5%	0.8%
Communication problems discussed	2%	2.2%	1.7%
If needed, tools used to address situations of tension/conflict			
Focus on objectives	4.3%	4.8%	2.9%
Focus on words used (rewording)	4.2%	3.1%	3.3%
Role playing	2.2%	1.3%	1%
3. Self-efficacy			
Overall, self-efficacy was addressed	62.1%	52.1%	52.3%
Depending on context and family's needs			
Self-care	28.4%	21.3%	25.9%
Stress factors	25.3%	18.2%	19%
Role adjustment	1.5%	0.6%	0.2%
Sadness and loss	14.6%	7.1%	3.2%
Identify family's strengths	35.9%	31.1%	29.5%
Referral to psychologist, social worker or other consultant	11.7%	7%	9.3%
Referral to online tools/websites	8.9%	3.4%	1.4%
B. Meetings and intervention delays, mean unless reported otherwise			
In ICU, face to face meetings between ICU team and family members set up by facilitators	2 [1; 4]	–	–
Number of End-of-life family conferences in the ICU	78 conferences for 31 (15.7%) patients	–	–
Median time (days) of interaction with the facilitator since randomization	7 [3; 16]	21 [13; 41]	45 [28; 71]
Attempted contacts by the facilitator with family member	5 [3; 10]	4 [2; 6]	3 [1; 5]
Successful contacts by the facilitator with family member	5 [2; 9]	4 [2; 6]	2·5 [1; 5]

[a] Criteria for being a facilitator: nurse with ICU experience > 5 years; considered by investigators as a local champion in communication and family management; minimal prior training in communication; keen to be out of full time routine care for study period. Facilitators' training: communication/simulation with focus on values, preferences and goals of care; attachment theory and clinical implications; Mediation: tension and conflict resolution. Debriefing sessions with facilitators to discuss communication and research difficulties: once a month by clinical psychologist non-implicated in FCS study—for the first 3 months; once every 2 months until the end of the study

[b] Results are expressed as proportions of interventions led by facilitators. The data were reported by facilitators (daily checklist during the ICU stay, 2–3 checklists per week during hospital stay; 2–4 checklists per month post hospital stay)

Table 3 Family baseline characteristics and outcomes at 1, 3 and 6 months post-randomization

	Control group without facilitator	Intervention group with facilitator	Difference, mean or proportion (95% CI) Control-intervention	*p* value
Primary outcome				
HADS[a] depression subscale score, median [IQR] (min–max)				
Baseline	*N* = 179	*N* = 188		0.91
	8 [4; 12] (0; 21)	8.5 [4; 12] (0; 21)		
1 month	*N* = 139	*N* = 145	− 0.99 (− 2.18; 0.20)	
	4 [2; 8.5] (0; 21)	6 [2; 10] (0; 21)		
3 months	*N* = 132	*N* = 132	− 0.97 (− 2.13; 0.20)	
	3 [1; 7] (0; 19)	4 [2; 7] (0; 21)		
6 months	*N* = 122	*N* = 138	0.53 (− 0.48; 1.55)	
	3 [1; 6.8] (0; 21)	3 [1; 6] (0; 16)		
Secondary outcomes				
HADS score, median [IQR] (min–max)				
Baseline	*N* = 179	*N* = 188		0.45
	20 [13; 26] (1; 40)	20 [13; 25] (1; 40)		
1 month	*N* = 139	*N* = 145	− 1.36 (− 3.48; 0.71)	
	11 [6; 18] (0; 38)	14 [7; 21] (0; 35)		
3 months	*N* = 132	*N* = 132	− 1.44 (− 3.53; 0.67)	
	9.5 [4; 17.2] (0; 37)	11 [6; 18] (0; 36)		
6 months	*N* = 122	*N* = 138	0.42 (− 1.51; 2.35)	
	8 [4; 15] (0; 39)	9 [4; 13.4] (0; 33)		
HADS anxiety subscale score, median [IQR] (min–max)				
Baseline	*N* = 179	*N* = 188		0.26
	11 [7; 15] (0; 21)	11 [8; 14.2] (0; 21)		
1 month	*N* = 139	*N* = 145	− 0.37 (− 1.49; 0.73)	
	6 [3.5; 10] (0; 19)	7 [4; 12] (0; 18)		
3 months	*N* = 132	*N* = 132	− 0.47 (− 1.57; 0.63)	
	6 [3; 10] (0; 19)	7 [4; 10] (0; 17)		
6 months	*N* = 122	*N* = 138	− 0.11 (− 1.23; 1.01)	
	5 [3; 9] (0; 19)	5 [3; 8] (0; 20)		
IES-6[b] score, median [IQR] (min–max)				
1 month	*N* = 139	*N* = 145	− 0.02 (− 2.08; 0.39)	0.76
	6 [3; 12] (0; 24)	7 [3; 11] (0; 24)		
3 months	*N* = 132	*N* = 132	− 0.84 (− 1.52; 0.88)	
	4 [1; 9] (0; 22)	5 [2; 9] (0; 22)		
6 months	*N* = 122	*N* = 138	− 0.33 (− 1.53; 0.88)	
	3 [1; 8] (0; 21)	3.5 [1; 7] (0; 20)		
Goal concordant care- support questions[c]				
Baseline	72/151 (47.7%)	65/158 (41.1%)		
1 month	50/105 (47.6%)	50/113 (44.2%)	3.4% (− 10.8%; 17.5%)	0.59
3 months	28/83 (33.7%)	35/81 (43.2%)	− 9.5% (− 25.5%: 6.6%)	
6 months	35/80 (43.8%)	37/83 (44.6%)	− 0.8% (− 16.9%; 15.2%)	
Experience of serious illness QUAL-E—relationship with HCPs[d]				
Baseline	9 [6; 11] (4; 15)	8 [5; 11] (4; 17)		0.64
1 month	10 [6; 13] (4; 20)	9 [6; 13] (4; 20)	0.26 (− 0.85; 1.39)	
3 months	12 [8; 19] (4; 20)	13 [6; 19] (4; 20)	0.24 (− 1.50; 1.98)	
6 months	11 [7; 18] (4; 20)	13 [8; 18] (4; 20)	− 0.74 (− 2.46; 0.97)	
Experience of serious illness QUAL-E—completion[d]				
Baseline	7 [4; 9] (3; 15)	6 [4; 8] (3; 15)		0.76

Table 3 (continued)

	Control group without facilitator	Intervention group with facilitator	Difference, mean or proportion (95% CI) Control-intervention	*p* value
1 month	6 [4; 9] (3; 15)	6 [4; 8] (3; 15)	0.66 (— 0.02; 1.35)	
3 months	6 [4; 7] (3; 14)	6 [4; 8] (3; 14)	— 0.11 (— 0.92; 0.69)	
6 months	6 [4; 8] (3; 14)	6 [4; 7] (3; 14)	0.19 (— 0.63; 1.01)	
Experience of serious illness QUAL-E—preparedness[d]				
Baseline	10 [9; 12] (6; 16)	11 [9; 12] (6; 17)		0.86
1 month	11 [10; 13] (6; 19)	12 [10; 13] (5; 19)	0.03 (— 0.57; 0.63)	
3 months	11 [9; 13] (5; 20)	11 [10; 14] (6; 19)	— 0.38 (— 1.18: 0.43)	
6 months	11 [9; 12] (8; 16)	11 [10; 15] (7; 15)	— 0.02 (— 0.67; 0.64)	
Health related quality of life (SF-1)[e]				
Baseline	3 [2; 3] (1; 5)	3 [2; 3] (1; 5)		0.43
1 month	4 [3; 4] (1; 5)	4 [3; 4] (2; 5)	— 0.12 (— 0.33; 0.08)	
3 months	3 [3; 4] (1; 5)	3 [3; 4] (1; 5)	0.13 (— 0.08; 0.35)	
6 months	3 [3; 4] (1; 5)	3 [3; 4] (1; 5)	0.07 (— 0.15; 0.30)	

[a] HADS: symptoms of anxiety and depression were measured using the HADS symptom score which uses 14 self-reported items (7 for depression and 7 for anxiety) to produce a total score ranging from 0 to 42 with the subscales for depression and anxiety ranging from 0 (least) to 21 (most)

[b] IES-6: post-traumatic stress symptoms were assessed using the Impact of Events Scale-6 (IES-6). Each item is scored on a 4-point scale that addresses symptom severity from "not at all" to "extremely", ranging from 0 to 24

[c] Goal concordant care: concordance between the care patients want and the care they are receiving was measured with two questions. 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 focussed 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 focussed 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. "No not know" answers were assigned to "discordant"

[d] QUAL-E (family): quality of life was measured using the QUAL-E (family) that includes 17 items in 3 domains (relationship with healthcare providers, completion and preparedness)

[e] SF-1: Health related quality of life was measured using the SF-1, a shorter version of the functional health status scale adapted from the SF-12

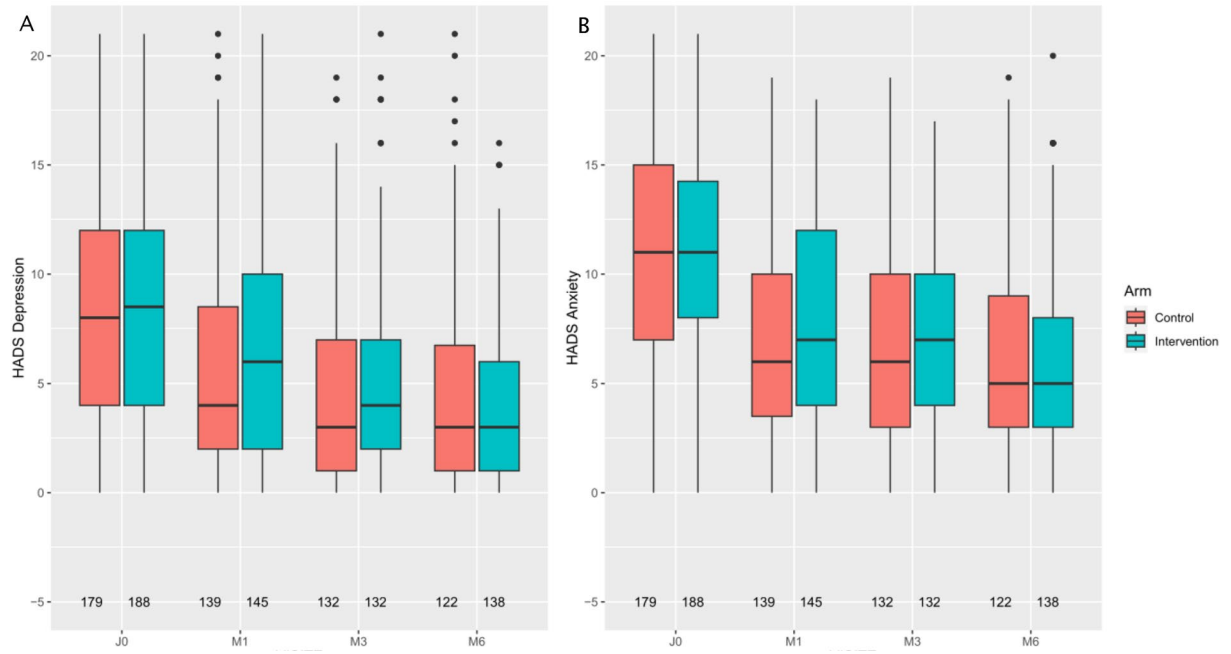

Fig. 2 Symptoms of depression and anxiety over 6 months in the control and the intervention group

disentangle. Last, the facilitator's role was to nurture partnerships with families but in doing so they may have unintentionally generated distance between the family and the ICU team, raising pertinent questions regarding the facilitator's precise role and place within the healthcare framework. Qualitative investigations will help understand these dynamics.

To sum up, a nurse facilitator did not yield the expected reduction in family depression symptoms and other secondary endpoints. This trial serves as a clarion call for ongoing innovation in devising proactive interventions that target psychological burden and goal-concordant care. The convergence of our findings with prior research provides guidance for future trials aimed at enhancing the well-being of families facing serious illness. Effective interventions to alleviate the family psychological burden will need to target the few modifiable factors associated with anxiety, depression and PTSD in family members of the most vulnerable and the sickest critically ill patients.

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Author contributions
JRC, NKB, RE and EA wrote the study protocol. LB and MRR designed the study, planned and did the statistical analysis. All co-authors approved the study protocol. NKB wrote the first draft of the report with input from EA, MMR, RE, LB, and FP. JR, AC, AL, OH, TG, AR, VS, PC, FD, LL, SL, and AR provided substantial contribution to the acquisition of data. EA and NKB accessed and verified the data. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

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Data availability
Access to data and data analysis: EA and MR-R had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. MR-R from the Saint-Louis hospital Paris, France, conducted and is responsible for the data analysis. Data sharing: according to the Sponsor rules, the AP-HP is the owner of the data and no use or transmission to a third party can be made without its prior agreement. The steering committee will facilitate the use of the data and approval will not be unreasonably withheld. De-identified participant data will be made available to bona fide researchers registered with an appropriate institution within 3 months of publication. However, the steering committee will need to be satisfied that any proposed publication is of high quality, honours the commitments made to the participants in the consent documentation and ethical approvals, and is compliant with relevant legal and regulatory requirements (e.g. relating to data protection and privacy). The steering committee will have the right to review and comment on any draft manuscripts before publication.

Declarations

Conflicts of interest
NK-B reported grants from French Ministry of Health during the conduct of the study and outside the submitted work. EA reported receipt of personal fees (lectures) from Pfizer, Gilead, Baxter, and Alexion; and institutional research grants from Merck Sharp and Dohme, Pfizer, Baxter, and Alexion outside the submitted work. AC received fees for conferences from Bard, outside the submitted work. All the other Authors have no conflict of interest to declare.

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