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# Questions to improve family–staff communication in the ICU: a randomized controlled trial

Elie Azoulay<sup>1\*</sup>, Jean-Marie Forel<sup>2</sup>, Isabelle Vinatier<sup>7</sup>, Romain Truillet<sup>12</sup>, Anne Renault<sup>3</sup>, Sandrine Valade<sup>1</sup>, Samir Jaber<sup>1</sup>, Jacques Durand-Gasselín<sup>8</sup>, Carole Schwebel<sup>4</sup>, Hughes Georges<sup>9</sup>, Sybille Merceron<sup>10</sup>, Alain Cariou<sup>5</sup>, Myriam Moussa<sup>2</sup>, Sami Hraiech<sup>2</sup>, Laurent Argaud<sup>6</sup>, Marc Leone<sup>1</sup>, J. Randall Curtis<sup>11</sup>, Nancy Kentish-Barnes<sup>1</sup>, Elisabeth Jouve<sup>12</sup> and Laurent Papazian<sup>2</sup>

## Abstract

**Purpose:** Relatives of intensive care unit (ICU) patients suffer emotional distress that impairs their ability to acquire the information they need from the staff. We sought to evaluate whether providing relatives with a list of important questions was associated with better comprehension on day 5.

**Methods:** Randomized, parallel-group trial. Relatives of mechanically ventilated patients were included from 14 hospitals belonging to the FAMIREA study group in France. A validated list of 21 questions was handed to the relatives immediately after randomization. The primary endpoint was comprehension on day 5. Secondary endpoints were satisfaction (Critical Care Family Needs Inventory, CCFNI) and symptoms of anxiety and depression (Hospital Anxiety and Depression Scale, HADS).

**Results:** Of 394 randomized relatives, 302 underwent the day-5 assessment of all outcomes. Day-5 family comprehension was adequate in 68 (44.2%) and 75 (50.7%) intervention and control group relatives ( $P=0.30$ ), respectively. Over the first five ICU days, median number of family–staff meetings/patient was 6 [3–9], median total meeting time was 72.5 [35–110] min, and relatives asked a median of 20 [8–33] questions including 11 [6–13] from the list, with no between-group difference. Satisfaction and anxiety/depression symptoms were not significantly different between groups. The only variable significantly associated with better day-5 comprehension by multivariable analysis was a higher total number of questions asked before day 5.

**Conclusions:** Providing relatives with a list of questions did not improve day-5 comprehension, secondary endpoints, or information time. Further research is needed to help families obtain the information they need.

**Trial registration:** ClinicalTrials.gov Identifier: NCT02410538.

**keywords:** Communication, Burden, Intensive care unit, Stress, Anxiety, Depression

\*Correspondence: [elie.azoulay@aphp.fr](mailto:elie.azoulay@aphp.fr)

<sup>1</sup> Medical Intensive Care Unit, APHP, Hôpital Saint-Louis, ECSTRA Team, and Clinical Epidemiology, UMR 1153 (Center of Epidemiology and Biostatistics Sorbonne Paris Cité, CRESS), INSERM, Paris Diderot Sorbonne University, Paris, France

Full author information is available at the end of the article

## Introduction

Over the last two decades, family members have become major partners in the delivery of critical care [1]. Increased awareness that relatives suffer acute emotional distress during the ICU stay of their loved one [2–5] and are subsequently at high risk of psychological burden [6] has prompted the development of strategies to improve interactions between families and ICU staff [5, 7, 8]. Strategies tested to date have targeted communication, behaviors, or palliative care. In the 1990s, the SUPPORT investigators reported that enhancing opportunities for patient–physician communication may be inadequate and suggested that proactive patient and family support may be needed [9]. A trial in relatives of patients at high risk of death showed that the intervention of facilitators trained to support communication between staff and families, adapt communication to each family's needs, and mediate conflicts led to a reduction in symptoms of depression in family members [8]. Similarly, a proactive communication strategy in relatives of patients dying in the ICU was shown to increase the time spent communicating with families and to lessen the burden associated with bereavement [5].

Another means of enhancing communication may be to help relatives identify their own informational needs so that they can seek appropriate answers. In 2011, using a mixed methodology study, we developed a list of 21 questions selected on the basis of ratings by relatives and staff [10]. Conceivably, such a list might help families to identify the questions to which they want answers. The list may also be useful to staff members to check the completeness of the information they provide to families. The main objective of such an approach would be to improve family comprehension, which is inadequate in up to 50% of cases, yet vital to family decision-making [7, 11, 12]. Comprehension of the diagnosis, prognosis, and treatment in the patient is an important outcome of ICU communication and should be seen as a marker for high-quality family-centered care [7, 11, 12]. A list of questions provided early to family members could encourage them to get prepared in advance and to ask questions relevant to their situation. As family comprehension might also result from interactions with other relatives and friends, we chose to provide the list to relatives rather than to clinicians.

The objective of this multicenter randomized controlled trial was to assess whether providing relatives with the list of 21 questions improved their comprehension. Relatives of patients in 14 ICUs were randomly assigned to receive the list or not. Staff members were encouraged to answer all questions asked by any of the relatives, every day and during a formal conference held

Relatives of ICU patients often have poor comprehension of the diagnosis, prognosis, and/or treatment of their loved one. Giving relatives a list of important questions they may want to ask during the ICU stay did not improve comprehension 5 days later. The only factor significantly associated with better comprehension was a higher number of questions asked within the first 5 days; this number was not significantly different between groups.

on day 3. Comprehension and secondary outcomes were assessed on day 5 during a face-to-face interview with research staff blinded to randomization results.

## Patients and methods

### Study design

From April 1, 2014 to April 15, 2016, we conducted a randomized, parallel-group trial at seven university and seven non-university hospitals belonging to the FAMIREA study group [5, 13, 14] in France (Appendix 1 in the electronic supplementary material, ESM). The study protocol was approved by the appropriate ethics committee (IFR 48 #13-004, Marseille) and French health authorities (CNIL DR-2013-497; CCTIRS 13.332). The trial was registered on ClinicalTrials.gov (NCT02410538). Informed consent was obtained from all participants.

### Patients and relatives

Patients were eligible if they received invasive mechanical ventilation within 48 h after ICU admission, were at least 18 years of age, received at least one family visit within 24 h following intubation, had a SAPS-II score less than 75, and were expected to survive for at least 5 days. For each patient, a single relative (the designated healthcare proxy) was included. Relatives were eligible if they could speak and read French.

### Randomization

Eligible relatives who provided informed consent were randomly assigned in a 1:1 ratio to the intervention or control group within 24 h after intubation. Details are given in the ESM.

### Study intervention

In the intervention group, the list of 21 questions was handed to the relative who provided informed consent immediately after randomization. Details on the list are available in the ESM.

### Study outcomes and data collection

The primary study outcome was family comprehension assessed on day 5 as previously described during an

interview with the local investigator, a physician blinded to random assignment [7, 11, 12]. The relative was asked about the main diagnosis, main treatments received, and likelihood of survival. Adequate understanding of these three components defined good comprehension. Secondary outcomes were also assessed on day 5 and included family satisfaction assessed using the Critical Care Family Needs Inventory (CCFNI) [4] and the prevalence of anxiety and depression subscores greater than 10 on the Hospital Anxiety and Depression Scale (HADS) [2, 3, 15]. A family–staff meeting was defined as a meeting that included at least one physician and at least one family member. Assessments of the family–staff meetings and communication in those meetings were performed by the local investigator (who was not the physician in charge).

Data collection is detailed in the ESM.

### Statistical analysis

We sought to detect a 20% increase in the proportion of relatives with good comprehension on day 5, from 60% to 80%, with the intervention [7, 16]. With the two-sided chi-square test and  $\alpha$  set at 0.05, we needed 218 relatives to detect the aforementioned difference with 90% power. To account for attrition, we planned to randomize 300 relatives using the arcsine correction for non-normality of the data. We finally randomized 394 patients. The intent-to-treat approach was used.

Continuous variables were described as median [25th–75th centiles] and categorical variables as  $n$  (%). Between-group comparisons were performed with the chi-square test for the primary outcome, Poisson regression model for the CCFNI score (the offset variable was the time spent with the relatives during the 5 days), and Wilcoxon rank-sum test for the HADS subscores (continuous non-Gaussian variable). The proportion of relatives with HADS subscores greater than 10 for anxiety and depression were compared between groups using the chi-square test. Associations linking number of family meetings, information time, and number of questions to comprehension were evaluated using the Wilcoxon rank-sum test. A logistic model was used to identify factors related to comprehension in multivariable analysis. Odd ratios (ORs) were presented with 95% confidence interval. All  $P$  values were two-sided, and the significance level was 0.05. SAS software (version 9.4, SAS Inc., Cary, NC) was used.

### Results

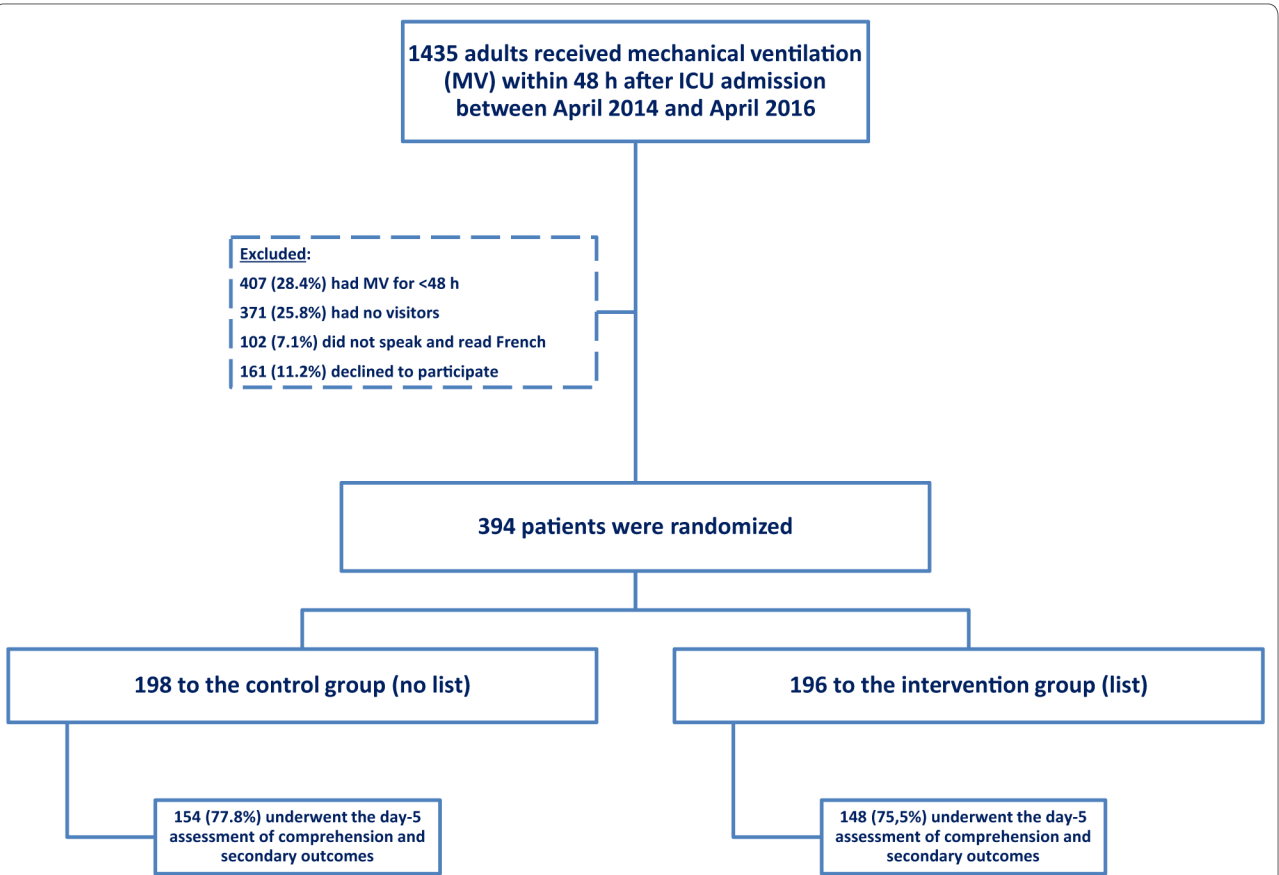
Of the 394 randomized relatives, 302 (76.6%) underwent the day-5 assessment of the outcome measures, 148 in the intervention group and 154 in the control group. Figure 1 shows the patient flow diagram. The characteristics of the patients and relatives were not significantly

different in the groups that did and did not undergo the day-5 assessment.

Table 1 describes the baseline patient characteristics. The most common diagnoses were shock (18%), exacerbation of chronic obstructive pulmonary disease (18%), pneumonia (15%), acute respiratory distress syndrome (13%), coma (9%), and cardiac arrest (7%). Median time to randomization of the relatives was 0 [0–1] days after ICU admission and 0 [0–0] days after intubation. The list of questions was provided to the relatives from the intervention group immediately after randomization. Table 2 reports the characteristics of the relatives. Half the relatives were spouses, one in four had no experience with having a loved one in the hospital, and 89% had no experience with having a loved one in the ICU. Among the relatives, three-fifths were receiving follow-up for a health condition and two-fifths were taking medications daily.

The number of family–staff meetings between randomization and day 5 ranged from 0 to 21 (Fig. 2). In the intervention and control groups, the median number of meetings per family was 6 [2–9] and 6 [3–10], respectively ( $P=0.06$ ) (Table 2) and the median information time was 70 [30–105] min and 78 [40–110] min, respectively ( $P=0.18$ ). The median number of physician–family member meetings that did not include a nurse was lower in the intervention group than in the control group (3 [1–5] vs. 4 [2–5],  $P=0.04$ ). Information time was 40 [15–55] vs. 45 [20–65] min in the intervention and control groups, respectively ( $P=0.05$ ). The median number of questions asked by relatives was 20 [8–33] overall, including 11 [6–13] from the list, with no difference between groups ( $P=0.89$ ).

All but 17 (6%) relatives attended the day-3 conference, which occurred 3 [3–3] days after randomization. This conference was scheduled in advance by the staff and relatives in 40.4% of cases and improvised in 59.6% of cases. Only one of the variables depicting the day-3 conference differed significantly between the two groups, namely, the proportion of relatives who expressed gratitude, which was 63% in the intervention group and 49.6% in the control group ( $P=0.02$ ). More than one relative attended the family meeting in 87 (56.5%) cases in the intervention group and 95 (64.2%) cases in the control group. Similarly, more than one ICU staff member attended the family meeting in 121 (78.6%) cases in the intervention group and 105 (70.9%) cases in the control group. The staff members attending the conference included more than one ICU physicians in 26.6% and 22.3% of cases in the intervention and control groups, respectively. Median duration of the day-3 meeting was 15 [10–20] min and 13 [8–20] min in the intervention and the control groups, respectively ( $P=0.23$ ). The percentage of day-3



**Fig. 1** Flow diagram. Among the 394 randomized patients, 92 were not interviewed at day 5, 48 in the intervention group and 44 in the control group. Of those, two denied consent after having initially agreed (one in each group), and 90 (47 and 43 in the intervention group and the control group, respectively) were discharged by day 5, including 33 patients who died (17 and 16 in the intervention group and the control group, respectively)

conference time during which relatives spoke was 0–25% in 27.7%, 26–50% in 49.8%, and more than 50% in 21.7% cases overall, with no difference between groups. During the day-3 conference, relatives vented emotions in 58.9%, expressed relief in 43.9%, remained silent for more than 1 min in 29.5%, cried in 17.9%, and expressed guilt in 10.2% cases overall, with no differences between the two groups.

### Primary and secondary outcomes

The day-5 assessment of family comprehension was performed in 148 (75.5%) and 154 (77.8%) relatives in the intervention and control groups, respectively ( $P=0.30$ ). Fewer than half the relatives had good comprehension, with no significant difference between groups. Neither were satisfaction and symptoms of anxiety and depression significantly different between the two groups (Fig. E1 in ESM). There were no differences in outcomes according to admission diagnosis (Table 3). Similarly, neither relationship to the patient nor level of education

was significantly associated with comprehension or the impact of the intervention. There was no center effect on the primary outcome.

Longer duration of the day-3 family conference showed a trend toward an association with better comprehension (15 [10–20] min for relatives with and 12 [10–20] min in those without good comprehension,  $P=0.06$ ). As shown in Fig. 3, more information time was significantly associated with better comprehension only in the intervention group. Similarly, the proportion of relatives with good comprehension increased with the number of family meetings over the first 5 days (7 [4–10] vs. 5 [2–8],  $P<0.0001$ ) and with the total meeting time (85 [50–110] min vs. 65 [20–105] min,  $P=0.004$ ). The number of questions from the list asked within the first 5 days was higher in relatives with good comprehension (12 [8–14] vs. 10 [5–12],  $P=0.003$ ). The total number of questions asked was significantly associated with good comprehension (25 [12–36] vs. 17 [7–30],  $P=0.002$ ). However, the proportion of meeting time during which relatives spoke

**Table 1 Patient characteristics at randomization, which occurred within 24 h after endotracheal intubation of the patient**

	Intervention group (N= 154)	Control group (N= 148)
Age (years)	61.5 [49.0–70.0]	62.0 [52.0–71.0]
Female gender	62 (40.3%)	56 (37.8%)
French descent	127 (82.5%)	122 (82.4%)
Time from ICU admission to randomization (days)	0.0 [0.0–1.0]	1.0 [0.0–1.0]
Attended high school or university	31 (20.1%)	27 (18.2%)
Time from intubation to inclusion (days)	0.0 [0.0–0.0]	0.0 [0.0–0.0]
Poor performance status	43 (27.9%)	45 (30.4%)
<b>Comorbidities</b>		
Chronic obstructive pulmonary disease	33 (21.4%)	27 (18.2%)
Chronic heart failure	14 (9.1%)	14 (9.5%)
Immunodeficiency	31 (20.1%)	37 (25%)
SAPS-II score at ICU admission	49.0 [39.0–62.0]	52.0 [40.0–61.0]
Direct admission to the ICU	74 (48.1%)	56 (37.8%)
<b>Reasons for ICU admission</b>		
Acute respiratory failure	86 (55.8%)	87 (58.8%)
Shock/sepsis	77 (50.0%)	74 (50.0%)
Acute kidney injury	23 (14.9%)	27 (18.2%)
Acute heart failure/cardiac arrest	29 (18.8%)	21 (14.2%)
Coma/trauma	52 (33.8%)	45 (30.4%)
Acute liver injury/hematological disorder	15 (9.7%)	18 (12.2%)
<b>Major treatments implemented within 5 days of ICU admission</b>		
Mechanical ventilation	154 (100%)	148 (100%)
Antibiotics	138 (90%)	135 (91%)
Vasoactive drugs	125 (81%)	121 (82%)
Deep sedation/light sedation/neuromuscular blockade	147 (95%)	143 (97%)
Surgery	28 (18%)	34 (23%)
Renal replacement therapy	15 (10%)	25 (17%)
Prone positioning/ECMO	0 (%) / 4 (%)	4 (%) / 5 (%)
Chemotherapy/immunosuppressive drugs	25 (16%)	24 (16%)
Blood transfusion	37 (24%)	41 (28%)

The data are median [interquartile range] or number (%). None of the comparisons between the intervention and control groups showed statistically significant differences

ICU intensive care unit, SAPS-II Simplified Acute Physiology Score version II, ECMO extracorporeal membrane oxygenation

was associated neither with comprehension nor with satisfaction. By multivariable analysis, the only factor significantly associated with better comprehension was a higher number of questions asked within the first 5 days (odds ratio [OR] 1.07/additional question; 95% confidence interval [95% CI] 1.02–1.12). Even when forced into the model, the randomization group was not significantly associated with family comprehension (OR 1.31; 95% CI 0.82–2.07).

## Discussion

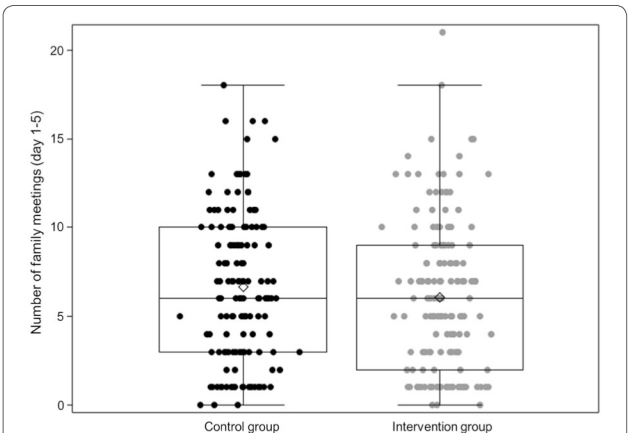
This randomized controlled trial assessed whether giving relatives a previously validated list of questions they can ask improved their comprehension of the

diagnosis, prognosis, and treatment in their loved one 5 days later. Giving the list, compared to no list, was not associated with any significant changes in comprehension on day 5 (primary outcome), family satisfaction, or presence in relatives of symptoms of anxiety and/or depression. The two groups showed no significant differences for the number of family meetings, total staff–family meeting time, or number of questions asked by relatives, or for the number of questions asked that were on the list. Importantly, the failure of the intervention to improve the primary outcome was obtained against a background of strong emphasis placed on staff–family interactions, with daily information and a routine day-3 conference. The parameters used to assess the quality of information (i.e., time

**Table 2 Characteristics of the relatives**

	Intervention group (N = 154)	Control group (N = 148)
<b>Relationship to the patient</b>		
Spouse/partner	75 (48.7%)	74 (50%)
Child	40 (26.0%)	46 (31.1%)
Parent	24 (15.6%)	24 (16.2%)
Other	15 (9.7%)	4 (2.7%)
Relative has one or more children	127 (82.5%)	119 (80.4%)
Age (years)	52.0 [42.0–63.0]	55.5 [41.0–62.0]
Female gender	100 (64.9%)	103 (68.9%)
French descent	130 (84.4%)	132 (89.2%)
Attended high school or university	52 (33.8%)	51 (34.5%)
Is or has a family member or close friend who is a healthcare professional	77 (50.0%)	80 (54.1%)
<b>Time needed to reach the hospital</b>		
≤ 30 min	88 (57.1%)	79 (53.4%)
31–60 min	36 (23.4%)	52 (35.1%)
1–2 h	18 (11.7%)	5 (3.4%)
> 2 h	2 (1.3%)	3 (2.0%)
Missing	10 (6.5%)	9 (6.1%)
First experience with having a loved one hospitalized/in the ICU	40 (26%)/137 (89%)	37 (25%)/132 (89%)
Receives follow-up for a health condition	94 (61.0%)	90 (60.8%)
Takes daily medications	71 (46.1%)	62 (41.9%)
Number of family meetings from randomization to day 5	6 [2–9]	6 [3–10]
Staff–relative meeting time from randomization to day 5 (min)	70 [30–105]	78 [40–110]
Number of questions from the list asked by the relative from randomization to day 5	11.0 [6.0–13.0]	11.0 [6.5–13.0]

The data are median [interquartile range] or number (%). None of the comparisons between the intervention and control groups showed statistically significant differences



**Fig. 2** Number of family meetings from randomization to the day-5 assessment in the intervention group and control group. The median [IQR] number of family meetings was 6 [2–9] and 6 [3–10] in the intervention and control groups, respectively ( $P = 0.06$ )

spent in daily meetings or in the day-3 conference) were all significantly associated with better day-5 comprehension.

Interventions that differ from ours in that they involve direct interaction with a specifically trained professional have been found effective. For instance, having a trained facilitator support communication between staff and families, adapt communication to family needs, and mediate conflicts was reported to diminish the burden of depression in relatives [8]. The use of a communication facilitator was perceived favorably by ICU staff in a qualitative interview study, which did not, however, include qualitative interviews of relatives [17]. In the SUPPORT study, having a specifically trained nurse encourage interaction between patients, families, and physicians without providing patient-specific guidance to physicians had no effect, suggesting that facilitators must provide such guidance to achieve improved communication [9].

A day-3 family conference was held with nearly all families in our study. Early information is important to develop a high-quality partnership with the family [12, 18]. Developing a consensus among all those involved regarding the goals of care in each individual patient is essential, particularly for patients with major comorbidities and those receiving a trial of ICU management [19, 20]. Early formal conferences held in a quiet room

**Table 3 Primary and secondary outcomes in the intervention and control groups**

	Intervention group (N = 154)	Control group (N = 148)	P value
<b>Primary outcome: comprehension on day 5</b>			
Proportion of relatives with good overall comprehension <sup>a</sup>	68 (44.2%)	75 (50.7%)	0.30
Proportion of relatives with good comprehension of each item			
Diagnosis	122 (79.2%)	111 (75.0%)	0.27
Prognosis	111 (72.1%)	110 (74.3%)	0.66
Treatment	111 (72.1%)	116 (78.4%)	0.21
Proportion of relatives with good comprehension of 0–3 items <sup>b</sup>			
0	3 (1.9%)	5 (3.4%)	0.48
1	26 (16.9%)	24 (16.2%)	
2	57 (37.0%)	44 (29.7%)	
3	68 (44.2%)	75 (50.7%)	
<b>Secondary outcomes</b>			
Satisfaction: CCFNI score	16.0 [14.0–19.0]	17.0 [15.0–20.0]	0.18
Hospital Anxiety and Depression Scale			
Anxiety subscale score	12.0 [9.0–15.0]	13.0 [9.0–15.0]	0.76
Relatives with symptoms of anxiety <sup>c</sup>	82 (58.6%)	89 (63.6%)	0.47
Depression subscale score	9 [5–13]	9 [5–13]	0.80
Relatives with symptoms of depression <sup>d</sup>	58 (41.4%)	59 (42.1%)	0.17

The data are median [interquartile range] or number (%)

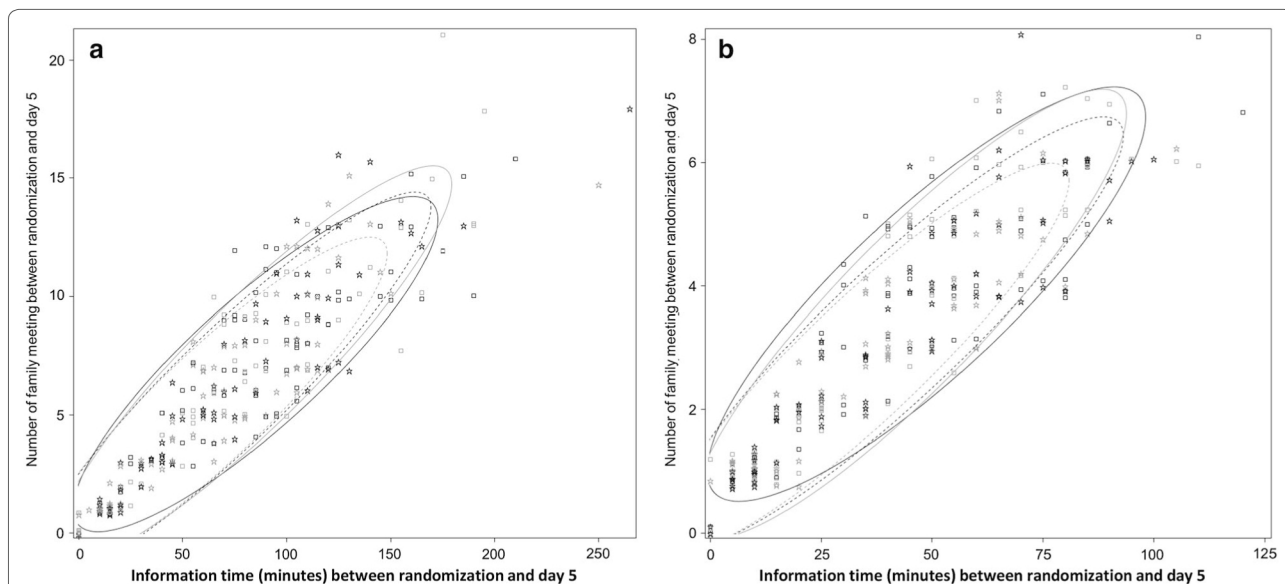
CCFNI Critical Care Family Needs Inventory

<sup>a</sup> Defined as comprehension of all three points: diagnosis, prognosis, and treatment

<sup>b</sup> Among diagnosis, prognosis, and treatment

<sup>c</sup> Defined as an anxiety subscale score greater than 10

<sup>d</sup> Defined as a depression subscale score greater than 10



**Fig. 3** Relationship between the number and the duration of family meetings from randomization to day 5 in the intervention group (gray) and control group (black). Squares indicate relatives with good comprehension (80% are within the solid-line ellipses). Stars indicate relatives without good comprehension (80% are within the dotted-line ellipses). Panel A displays information by nurses and/or physicians and panel B information by ICU physicians in charge of the patient. The figure shows that information time was longer in relatives with than without good comprehension in the intervention group but not in the control group



provide the opportunity to move from information to communication, by allowing relatives to ask questions, voice doubts and concerns, become aware that the staff wants to know about the patient as a person, and determine the role they want to play in the decision-making process. In our trial, more time spent with staff and relatives speaking together, including during the day-3 conference, was associated with improved comprehension. This finding supports a routine family conference early after ICU admission. Careful attention to how staff members inform and communicate with relatives is crucial. For instance, the proportion of family speech, number of questions asked, appropriateness of answers to relatives' needs, and parameters reflecting non-verbal communication should be monitored [4, 15, 21]. Moreover, the specific needs of relatives of patients at high risk of dying must be addressed [1, 21]. It is worth noting that in our trial only 13 patients had end-of-life decisions taken during the day-3 conference.

There are several reasons that this trial may not have improved comprehension and the other outcomes. First, the fact that the intervention had no effect may cast doubt on the validity of our specific list of questions or the approach of providing this list to relatives without additional guidance or support in using it. However, the list was composed of questions asked by a large sample of family members, who then evaluated how important these questions were to them [10]. We did not assess whether and how the list of questions was used by the relatives. Indeed, the inefficacy of the list could be ascribed to failure of relatives to read and use the list. Conceivably, having a staff member or facilitator go through the questions with relatives might have produced a different result. In addition, we did not assess the satisfaction of relatives with the list or the extent to which relatives felt the list was helpful. Qualitative interviews with relatives about the list might produce useful information to guide future interventions. Second, information time is the major determinant of comprehension and was not different between the two groups in our study, suggesting that the list alone, without also enhancing information time and quality, was ineffective. However, in the intervention group, more information time was associated with better comprehension which may reflect the fact that the question list helped relatives get more out of this communication.

This study has several additional limitations. First, the choice of comprehension as the primary outcome may deserve criticism. One could argue that if relatives feel acknowledged and supported by people they trust, it may not be so important for them to understand the medical issues. However, inadequate comprehension is a major determinant of post-ICU family syndrome [10].

Moreover, experiencing adequate comprehension may be the mandatory preliminary step before family participation in the decisions. The fact that despite advances in communication practices, poor comprehension is in the same range as studies performed two decades ago also suggests that physicians need training in communicating medical information. Lack of understanding can also be an adaptive mechanism to cope with the distressing situation. Another potential problem with this outcome lies in the assessment of comprehension and definition of good comprehension. However, for both these points, we used data from previous studies by our group [7, 12, 16] and others [11]. Second, the study was performed in France in ICUs who have been carrying out research on patient- and family-centered care for several decades [5, 7, 16, 22]. Whether the results apply to other ICUs is therefore unclear. However, half the ICUs were university and half non-university departments, and the patient case-mix was varied. Finally, as this study was randomized within ICUs at the patient level, there was a risk that the control group was contaminated by the intervention. Indeed, we cannot rule out biases such as sharing of the question list between intervention group and control group families in the waiting room, or clinician's bias for the provision of family information (including adequately answering their questions), since relatives from the intervention group received as much information time as those from the control group, nurses were involved in those meetings, but less information time was provided by the physicians. The lack of a center effect and the low comprehension rate argue against these biases being major contributors to failure of the intervention. However, we cannot deny that cluster randomization—that has its own limitations—might have been a stronger design for this study.

In conclusion, a list of important questions provided to the relatives failed to improve family comprehension, satisfaction, or anxiety and depression. Importantly, in this randomized controlled trial, relatives from both groups received the same information time and asked the same number of questions overall and from the list. Thus, the list did not prompt the relatives to seek more information time or to ask more questions. Failure of the list occurred against a background of strong attention to, time spent on, and experience of family-centered care. However, relatives' comprehension of the diagnosis, prognosis, and treatments of their critically ill family member is essential to effective shared decision-making and remains poor after decades of efforts to improve clinician-family communication in the ICU, suggesting that additional research is needed to identify methods to improve this comprehension. Having a facilitator use a list of common questions to help improve communication with relatives deserves evaluation.

## Author details

<sup>1</sup> Medical Intensive Care Unit, APHP, Hôpital Saint-Louis, ECSTRA Team, and Clinical Epidemiology, UMR 1153 (Center of Epidemiology and Biostatistics Sorbonne Paris Cité, CRESS), INSERM, Paris Diderot Sorbonne University, Paris, France. <sup>2</sup> Marseille AP-HM, Marseille Cedex 5, France. <sup>3</sup> Brest Hospital, Brest, France. <sup>4</sup> Grenoble Hospital, Grenoble, France. <sup>5</sup> Medical Intensive Care Unit, AP-HP, Cochin Hospital, Paris, France. <sup>6</sup> Lyon Hospital, Lyon, France. <sup>7</sup> Surgical ICUs From Montpellier or Marseille Hospitals, Medical-Surgical ICUs From La Roche sur Yon, La Roche sur Yon, France. <sup>8</sup> Toulon Hospital, Toulon, France. <sup>9</sup> Tourcoing Hospital, Tourcoing, France. <sup>10</sup> Versailles Hospital, Le Chesnay, France. <sup>11</sup> Cambia Palliative Care Center of Excellence, University of Washington, Seattle, USA. <sup>12</sup> Statistical Department of Marseille, AP-HM, Marseille, France.

## Author contributions

Authors have participated in the design (EA, LP, NKB, MM, EJ), acquisition (JMF, IV, AR, SV, SJ, JDG, CS, HG, SM, AC, SH, LA, ML), analysis (EA, LP, NKB, MM, EJ), and interpretation of the data (EA, LP, NKB, MM, EJ, JRC). All have participated in drafting and revising the paper. All approved the final version and all are accountable for all aspects of the work.

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## Compliance with ethical standards

## Conflicts of interest

Dr. Azoulay reports personal fees and other from Gilead, personal fees from Astellas, personal fees from Baxter, personal fees from Alexion, personal fees from Ablynx, outside the submitted work. Other authors declare no conflict of interest.

## Ethical standards

The study protocol was approved by the appropriate ethics committee (IFR 48 #13-004, Marseille) and French health authorities (CNIL DR-2013-497; CCTIRS 13.332). The trial was registered on ClinicalTrials.gov (NCT02410538). Informed consent was obtained from all participants.

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