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Effect of an ICU Diary on Posttraumatic Stress Disorder Symptoms Among Patients Receiving Mechanical Ventilation
A Randomized Clinical Trial

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IMPORTANCE Keeping a diary for patients while they are in the intensive care unit (ICU) might reduce their posttraumatic stress disorder (PTSD) symptoms.

OBJECTIVES To assess the effect of an ICU diary on the psychological consequences of an ICU hospitalization.

DESIGN, SETTING, AND PARTICIPANTS Assessor-blinded, multicenter, randomized clinical trial in 35 French ICUs from October 2015 to January 2017, with follow-up until July 2017. Among 2631 approached patients, 709 adult patients (with 1 family member each) who received mechanical ventilation within 48 hours after ICU admission for at least 2 days were eligible, 657 were randomized, and 339 were assessed 3 months after ICU discharge.

INTERVENTIONS Patients in the intervention group (n = 355) had an ICU diary filled in by clinicians and family members. Patients in the control group (n = 354) had usual ICU care without an ICU diary.

MAIN OUTCOMES AND MEASURES The primary outcome was significant PTSD symptoms, defined as an Impact Event Scale-Revised (IES-R) score greater than 22 (range, 0-88; a higher score indicates more severe symptoms), measured in patients 3 months after ICU discharge. Secondary outcomes, also measured at 3 months and compared between groups, included significant PTSD symptoms in family members; significant anxiety and depression symptoms in patients and family members, based on a Hospital Anxiety and Depression Scale score greater than 8 for each subscale (range, 0-42; higher scores indicate more severe symptoms; minimal clinically important difference, 2.5); and patient memories of the ICU stay, reported with the ICU memory tool.

RESULTS Among 657 patients who were randomized (median [interquartile range] age, 62 [51-70] years; 126 women [37.2%]), 339 (51.6%) completed the trial. At 3 months, significant PTSD symptoms were reported by 49 of 164 patients (29.9%) in the intervention group vs 60 of 175 (34.3%) in the control group (risk difference, −4% [95% CI, −15% to 6%]; $P = .39$). The median (interquartile range) IES-R score was 12 (5-25) in the intervention group vs 13 (6-27) in the control group (difference, −1.47 [95% CI, −1.93 to 4.87]; $P = .38$). There were no significant differences in any of the 6 prespecified comparative secondary outcomes.

CONCLUSIONS AND RELEVANCE Among patients who received mechanical ventilation in the ICU, the use of an ICU diary filled in by clinicians and family members did not significantly reduce the number of patients who reported significant PTSD symptoms at 3 months. These findings do not support the use of ICU diaries for preventing PTSD symptoms.

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Each year, millions of patients throughout the world survive a hospitalization that included a stay in an intensive care unit (ICU). ICU survivors can experience a variety of physical, cognitive, and emotional sequelae.[1,2] In particular, mental health disorders associated with an ICU stay include anxiety,[3] depression symptoms,[4] posttraumatic stress disorder (PTSD) symptoms,[5,6] and complicated grief for families.[7]

It is possible that impaired recall of the ICU stay, potentially accompanied by hallucinations or delusions, contributes to the posttraumatic stress.[8] Thus, use of an ICU diary given to the patient at discharge to consult at will could offer benefit.[9] By providing objective information to patients, which could help fill in memory gaps, ICU diaries have allowed them to abandon unrealistic experiences, reconstruct their experience,[10] gain a sense of reality,[11] and resolve differences in experience with their families.[12] However, studies exploring the usefulness of ICU diaries in preventing psychological post–intensive care syndrome were often conducted with small numbers of patients[13] or select samples[14] or with various design characteristics,[15] outcome measures, and length of follow-up that compromised comparision.[9,15]

This multicenter study was designed to assess the effect of an ICU diary on the occurrence of mental health consequences in patients and their families in the ICU setting.

Key Points

Question What is the effect of an intensive care unit (ICU) diary, filled out by family members and ICU clinicians, on posttraumatic stress disorder symptoms among patients receiving mechanical ventilation?

Findings In this randomized clinical trial of 657 patients, significant posttraumatic stress disorder symptoms at 3 months, defined as an Impact Event Scale-Revised score greater than 22 (range, 0-88; a higher score indicates more severe symptoms), occurred in 29.9% of patients in the ICU diary group and 34.3% of patients in the control group, a difference that did not reach statistical significance.

Meaning These findings do not support the use of ICU diaries for preventing posttraumatic stress disorder symptoms after ICU hospitalization.

Methods

Study Design and Oversight

This assessor-blinded, multicenter, randomized clinical trial compared the use of an ICU diary filled out by clinicians and family members during the ICU stay with usual care. Written informed consent was obtained from 1 family member (the closest to the patient; the patient's spouse, partner, children, parents, or other were considered in that order). In accordance with the French law, the ethics committee of Ile de France II approved the study on June 11, 2015, including delayed consent from patients unable to make decisions at the time of randomization. The trial protocol has been published[16] and is available in Supplement 1. The statistical analysis plan is available in Supplement 2.

Randomization

The patients were randomized in a 1:1 ratio into 2 groups, stratified by center, using a secure web-based random number generator to select permuted blocks, with a block size of 4.

Study Setting

ICUs with physician leaders who were members of the French Society of Intensive Care or French Society of Anesthesiology were recruited via the Outcomerea research network, a French nonprofit organizational research network. To be included, ICUs had to have more than 8 beds, a physician and nurse on staff in the ICU who would take responsibility for study organization, and agreement by the ICU clinicians that they would contribute to the diary if a patient was assigned to the intervention group and avoid use of a diary if the patient was assigned to the control group.

Study Participants

Inclusion Criteria

Consecutive patients who were undergoing mechanical ventilation were approached by the clinicians. Eligible patients had to be aged at least 18 years, receiving mechanical ventilation for at least 48 hours that was initiated within 48 hours of ICU admission, and have a family member present during the inclusion period and able to visit the patient during the ICU stay. Both the patient and family member had to have sufficient French-language skills for follow-up telephone interviews.

Exclusion Criteria

Patients were ineligible if they had no family members visiting them, were under legal guardianship, or had a preadmission diagnosis of psychosis or dementia. Also, patients with acute neurologic diseases, with cardiac arrest at admission, who were mute or deaf, and whose status was considered by the investigator as highly likely to lead to death or withdrawal of life support within 48 hours were excluded. Patients included in another trial with a telephone interview after ICU discharge were also excluded.

Study Intervention

The intervention tested was an ICU diary completed by clinicians and family members of patients in the ICU. A description of the content and writing guidelines is available in the eMethods in Supplement 3. Prior to patient transfer out of the ICU, a concluding note was written by an ICU clinician. The ICU diary was detailed to the patient in the ICU room a few days before discharge and was given to the patient or, if the patient was confused, to the family member who consented to the study at or as close as possible to the day of discharge. In cases in which the patient died, the diary was concluded with a condolence letter and mailed to the family. To promote adherence to the intervention, the central study coordinating team held an educational meeting with clinicians in each center, the local physician and nurse coordinators monitored each diary, and the laboratory of psychopathology and health process coordinating center performed content analysis of a random sample of diaries. The control group received usual ICU care with no ICU diary.

Outcomes

Primary and secondary outcomes were measured by a psychologist (C.V.) hired for the study. The psychologist was blind to the randomization group when contacting patients and family members (the 1 family member per patient who consented to the study and provided a phone number). If a patient or family member spoke about the diary during the interview, the unblinded interview was registered.

Primary Outcomes

The primary outcome was PTSD symptoms in patients 3 months after ICU discharge, measured by the Impact of Event Scale-Revised (IES-R) questionnaire.[17] Significant PTSD symptoms were defined as an IES-R score greater than 22 (range, 0-88; higher scores indicate more severe symptoms).[15,18] There is no established minimal clinically important difference for the IES-R scale. Ancillary outcomes related to the primary outcome included the median IES-R score and scores for the 3 domains (intrusion, avoidance, and hyperarousal) that make up the IES-R score.

Secondary Outcomes

PTSD symptoms were evaluated in family members 3 months after ICU discharge, with significant symptoms defined as an IES-R score greater than 22.[17,18] Anxiety and depression syndromes in both patients and family members were evaluated 3 months after ICU discharge using the Hospital Anxiety and Depression Scale (HADS) score (range, 0-42; higher scores indicate worse symptoms). Significant anxiety and depression symptoms were defined as a score greater than 8 for anxiety and depression subscales (range for each subscale, 0-21).[19] The minimal clinically important difference was 2.5 for each subscale.[20]

Recollection of patient memories of the ICU stay was evaluated 3 months after ICU discharge by the validated ICU memory tool questionnaire.[21] The ICU memory tool questionnaire asked patients about specific factual (faces, family, alarms, voices, lights, darkness, clock, breathing tube, suctioning, tube in nose, and wards rounds), emotional (panic, pain, being uncomfortable, feeling confused, feeling anxious or frightened, and feeling down), and delusional (dreams, nightmares, hallucinations, and someone trying to harm) memories.

Content analysis of ICU diaries was described with a grid[15] that was developed using Delphi techniques by a panel of 11 members (3 ICU physicians of different units, 1 ICU nurse, 2 psychologists, 2 hospital visiting volunteers, 1 person from the general population with a history of admission to an ICU, and 1 former ICU patient and his wife) that described 6 categories (eTable 1 in Supplement 3). The content analysis of the diaries was performed by 4 psychologists (M.A.L., L.B., C.F., and L.F.).

Adverse Events

Adverse events were assessed during the telephone interview 3 months after discharge by the psychologist and reported to the relevant ICU clinical team in instances in which family members or patients needed psychological support.

Post Hoc Secondary Outcomes

The number of times the patient reported reading the diary was explored during an interview with the patient 6 months after ICU discharge. PTSD symptoms and anxiety and depression symptoms were assessed in family members of deceased patients.

Sample Size

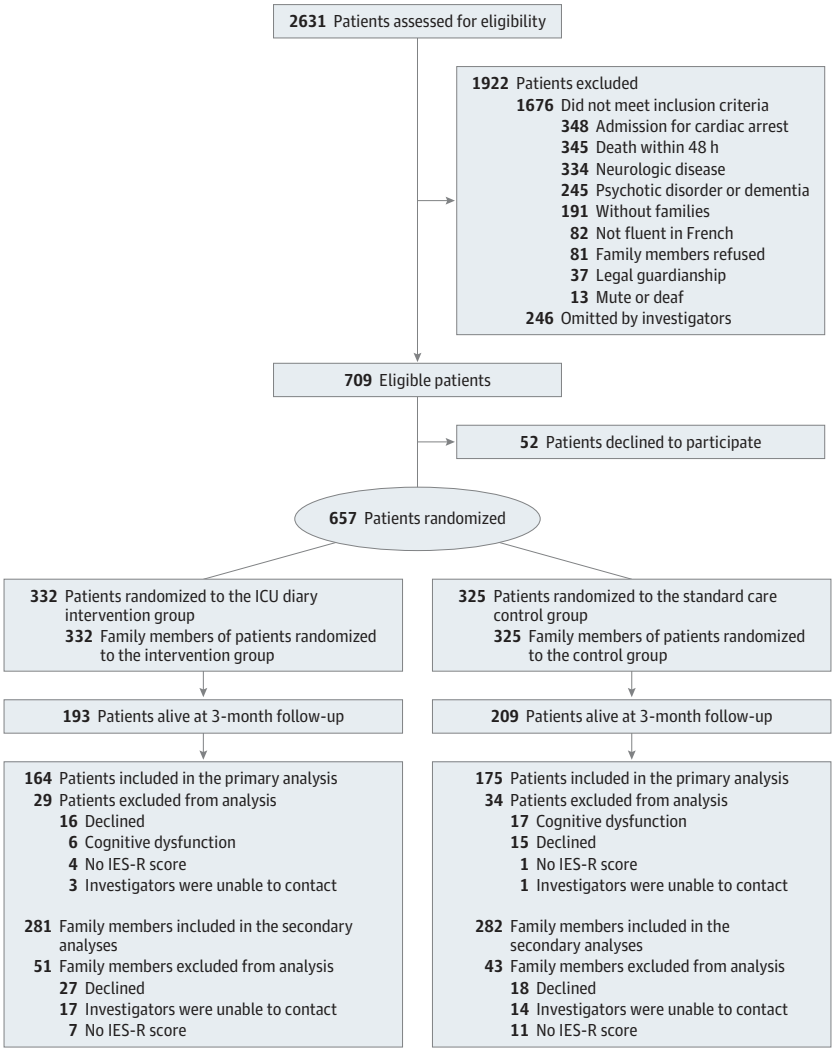
PTSD has been previously reported in 15% to 64%[9,15,18,22] of patients in the ICU and in 29.8% to 67%[5,15,18,23] of family members of patients in the ICU. We hypothesized that the rate of PTSD in patients (the percentage with an IES-R >22) would be 40% in the control group and 26% in the intervention group. To detect a difference of 14% between the 2 groups with a type I error of .05 and a power of 80%, 352 patients (176 in each group) were required at 3 months. Assuming an overall rate of 50% of mortality, re-hospitalization, or impossibility of interviewing the patient (eg, due to refusal, sequelae, or loss to follow-up), we included 700 patients and their family member in the 35 centers.

Statistical Analysis

Patients were analyzed according to their randomization group. For the primary outcome, the analysis sets constituted patients with a complete IES-R score at 3 months. For secondary outcomes, because additional missing values were rare, the analyses were performed with the same data set used for the primary outcome. Data are described as number and percent for qualitative variables and median and interquartile range (IQR) for quantitative variables. Comparisons between groups were performed using χ^2 tests for qualitative variables and the nonparametric Mann-Whitney test. The absolute differences in percentages for primary and secondary outcomes were computed with exact binomial CIs. To assess the effect of possible confounding on the IES-R score, 2 multivariable regressions were performed. The first considered the IES-R score as a continuous variable and was a generalized linear multivariable mixed model based on a negative binomial distribution with a random effect to account for clustering within centers. The goodness of fit of the model was assessed by the generalized χ^2. The second regression modeled the probability of an IES-R score of greater than 22 by using a stratified logistic regression. For both models, the variable selection was performed in 2 steps: a univariable regression was performed and variables with a *P* value less than .20 were considered for the multivariable analysis. The model with the minimum log-likelihood value was retained as the final model for the generalized linear multivariable mixed model. The final logistic model was determined by stepwise selection.

The generalized linear multivariable mixed model included the following variables: presence of a diary (forced), age, the Simplified Acute Physiology Score II, sex, duration of benzodiazepine exposure, duration of fentanyl exposure, weaning failure and reintubation, episode of delirium,[24] emotional memories, and delusional memories. The final logistic regression model included the following variables: presence of a diary (forced), age, sex, the Simplified Acute Physiology Score II, duration of propofol exposure, acute respiratory failure/chronic obstructive respiratory disease, emotional memories, and delusional memories.

Figure. Flow of Patients Included in a Study of the Effect of an Intensive Care Unit (ICU) Diary on Posttraumatic Stress Disorder Symptoms Among Patients Receiving Mechanical Ventilation



IES indicates Impact of Event Scale-Revised.

All analyses were performed by using SAS version 9.4 (SAS Institute). All statistical comparisons were performed using 2-sided tests, with a *P* value less than .05 considered significant. However, because of the potential for type I error due to multiple comparisons, findings for analyses of the secondary outcomes should be interpreted as exploratory.

Results

Study Population and Follow-up

All 35 ICUs recruited patients for 16 months, from October 2015 to January 2017 (**Figure**; eTable 2 and eTable 3 in Supplement 3). Follow-up was completed in July 2017. Three of the 35 ICUs were routinely using an ICU diary before the beginning of the trial. Overall, 709 patients were eligible. A total of 52 patients declined participation and 657 patients were randomized (325 in the control group and 332 in the intervention group). Follow-up at 3 months with full completion of the IES-R was obtained in 339 patients (51.6%; 175 in the control group and 164 in the intervention group) and 563 family members (85.6%; 282 in the control group and 281 in the intervention group). Baseline characteristics were similar between the eligible patients and patients who withdrew consent (eTable 4 in Supplement 3). Baseline characteristics were similar between patients and family members in the intervention and control groups (eTable 5 in Supplement 3) and between patients and family members in the outcome analysis in the intervention and control groups (**Table 1**).

Primary Outcome

The number of patients with an IES-R score greater than 22 was 49 of 164 (29.9%) in the intervention group vs 60 of 175 (34.3%) in the control group (risk difference, −4% [95% CI, −15% to 6%]; *P* = .39). For the ancillary outcomes related to the primary outcome measure, the median (IQR) IES-R score was 12 (5-25) in the intervention group vs 13 (6-27) in the control group (difference, −1.47 [95% CI, −1.93 to 4.87]; *P* = .38;

Table 1. Baseline Characteristics of Patients and Family Members Included in a Study of the Effect of an Intensive Care Unit (ICU) Diary on Posttraumatic Stress Disorder Symptoms Among Patients Receiving Mechanical Ventilation

Characteristic	No. (%) Intervention Group	Control Group
Patients[a]	**(n = 164)**	**(n = 175)**
Age, median (IQR), y	62.5 (49.5-70)	61 (51-70)
Sex		
Male	110 (67.1)	103 (58.9)
Female	54 (32.9)	72 (41.1)
SAPS II, median (IQR)[b]	51.5 (38.5-66.5)	53 (39-66)
Patient status		
Medical patient	122 (74.4)	138 (78.9)
Unscheduled surgery	35 (21.3)	31 (17.7)
Scheduled surgery	7 (4.3)	6 (3.4)
Main symptom at admission		
Acute respiratory failure/COPD	75 (45.7)	84 (48)
Shock and multi-organ failure	66 (40.2)	68 (38.8)
Coma	12 (7.3)	9 (5.1)
Trauma	7 (4.3)	5 (2.9)
Metabolic	2 (1.2)	2
Acute renal failure	1 (0.6)	0
Monitoring/scheduled surgery	1 (0.6)	7 (4)
ICU events		
Physical constraint	121 (73.8)	126 (72)
Episode of delirium[c]	56 (34.1)	58 (33.1)
Weaning failure and re-intubation	18 (11)	19 (10.9)
Self-extubation	11 (6.7)	13 (7.4)
Unexpected cardiac arrest	9 (5.5)	7 (4)
Fall	4 (2.4)	0
Prognosis[d]		
No fatal illness	125 (76.2)	132 (75.4)
Fatal illness within 5 y	35 (21.3)	38 (21.7)
Fatal illness within 1 y	4 (2.4)	5 (2.9)
Limitation of daily activity[e]		
None	79 (48.2)	89 (50.9)
Moderate	66 (40.2)	62 (35.4)
Severe	14 (8.5)	21 (12)
Total dependency	5 (3)	3 (1.7)
Treatment duration, median (IQR), d		
Mechanical ventilation	9 (6-15)	9 (5-15)
Noninvasive ventilation	0 (0-3)	0 (0-2)
Fentanyl	6 (3-11)	6 (3-10)
Benzodiazepines	3.5 (2-8.5)	4 (2-9)
Propofol	1 (0-3)	0 (0-3)
Duration of stay, median (IQR), d		
ICU	14 (9-22)	14 (9-24)
Hospital	29 (16-49)	27 (17-45)
DFLST	4 (2.4)	5 (2.9)
Discharge	164 (100)	175 (100)
Family Members	**(n = 281)**	**(n = 282)**
Age, median (IQR), y	56.5 (45-66)	55 (44.5-66)
Sex		
Male	73 (26)	86 (30.5)
Female	208 (74)	196 (69.5)
Relationship with the patient		
Spouse/partner	156 (55.5)	155 (55)
Children	84 (29.9)	86 (30.5)
Other	25 (8.9)	33 (11.7)
Parents	16 (5.7)	8 (2.8)
Occupation[f]	(n = 274)	(n = 277)
Primary	3 (1.1)	3 (1.1)
Secondary	9 (3.3)	23 (8.3)
Tertiary	181 (66.1)	172 (62.1)
None	22 (8.0)	21 (7.6)
Retired	59 (21.5)	58 (20.9)
Health occupation	35 (12.6)	30 (10.8)
Educational level	(n = 273)	(n = 272)
None	2 (0.73)	3 (1.1)
Upper secondary education	44 (16.1)	40 (14.7)
High school	56 (20.5)	56 (20.6)
Technical college	76 (27.8)	79 (29)
Associate degree	29 (10.6)	19 (7)
Bachelor degree	30 (11)	46 (16.9)
Master degree	36 (13.2)	29 (10.7)
Previous ICU hospitalization, No./total No. (%)	14/277 (5.1)	18/275 (6.5)

Abbreviations: COPD, chronic obstructive pulmonary disease; DFLST, decision to forgo life-sustaining treatments; IQR, interquartile range; SAPS, Simplified Acute Physiologic Score.

[a] Patients had no missing data.

[b] SAPS II is used to predict hospital mortality (range, 0-162; higher scores indicate higher likelihood of mortality).

[c] Episodes of delirium were diagnosed using the Confusion Assessment Method for the Intensive Care Unit.[24]

[d] Based on the McCabe score, which explores subjective prognosis of comorbid conditions at ICU admission.

[e] Based on the Acute Physiology and Chronic Health Evaluation score.

[f] Occupations were grouped into agricultural (primary), industrial (secondary), or commercial or related to administration or human health or public action (tertiary).

Table 2). Symptoms of intrusion, avoidance, and hyperarousal were not significantly different between the intervention and control groups in patients or family members (Table 2 and **Table 3**). During the interview, 2 patients spoke spontaneously of their diary to the psychologist.

Prespecified Secondary Outcomes

Symptoms of anxiety were reported by 51 of 163 patients (31.3%) in the intervention group vs 53 of 173 (30.6%) in the control

Table 2. Patient Outcomes at 3-Month Follow-up in a Study of the Effect of an Intensive Care Unit (ICU) Diary on Posttraumatic Stress Disorder Symptoms Among Patients Receiving Mechanical Ventilation

Outcomes	No. (%)		Risk Difference, % (95% CI)[a]	Difference (95% CI)[a]	*P* Value
	Intervention Group	Control Group			
Primary outcome	**(n = 164)**	**(n = 175)**			
Presence of PTSD symptoms (IES-R score>22)[b]	49 (29.9)	60 (34.3)	−4 (−15 to 6)		.39
IES-R score, median (IQR)[b]	12 (5 to 25)	13 (6 to 27)		−1.47 (−1.93 to 4.87)	.38
IES-R domain scores, median (IQR)					
Intrusion	5 (2-9)	5 (2-11)		−0.25 (−1.64 to 1.12)	.74
Avoidance	4 (1-10)	5 (2-10)		−1.01 (−2.35 to 0.33)	.08
Hyperarousal	2 (0-6)	2 (0-5)		−0.08 (−1.11 to 0.94)	.64
Secondary outcomes					
Depression and anxiety symptoms[c]	(n = 163)	(n = 173)			
HADS score, median (IQR)	9 (5-14)	9 (5-13)		−0.75 (−2.27 to 0.78)	.30
HADS-Anxiety score	5 (2-8)	6 (2-8)		−0.36 (−1.22 to 0.50)	.72
HADS-Depression score	4 (1-7)	3 (2-7)		−0.39 (−1.29 to 0.52)	.66
Symptoms of anxiety			0.7 (−9 to 11)		.91
Yes	51 (31.3)	53 (30.6)			
No	112 (68.7)	120 (69.4)			
Symptoms of depression			5 (−5 to 13)		.35
Yes	31 (19)	41 (23.7)			
No	132 (81)	132 (76.3)			
Memories of the ICU stay[d]	(n = 158)	(n = 161)			
Factual memories	141 (89.2)	143 (88.8)	0.4 (−7 to 8)		.90
Median (IQR)	5 (2 to 8)	6 (3 to 8)		−0.32 (−1.03 to 0.39)	.44
Emotional memories	119 (75.3)	127 (78.9)	4 (−6 to 13)		.45
Median (IQR)	2 (1-4)	2 (1 to 4)		−0.15 (−0.58 to 0.27)	.51
Delusional memories	106 (67.1)	108 (67.1)	0 (−11 to 11)		>.99
Median (IQR)	1 (0-2)	2 (0-2)		−0.07 (−0.35 to 0.22)	.57
Memories of the hospital stay before ICU admission	(n = 158)	(n = 161)	3 (−6 to 13)		.50
Not at all	82 (51.9)	74 (46)			
Clearly	51 (32.3)	55 (34.2)			
Vaguely	25 (15.8)	32 (19.9)			
Memory of being in the ICU	(n = 158)	(n = 161)	6 (−4 to 17)		.23
Yes	102 (64.6)	114 (70.8)			
No	56 (35.4)	47 (29.2)			
Memories of transfer from ICU to ward	(n = 158)	(n = 161)	−3 (−11 to 5)		.56
Not at all	31(19.6)	27 (16.8)			
Clearly	104 (65.8)	104 (64.6)			
Vaguely	23 (14.6)	30 (18.6)			
Unexplained feelings of panic and apprehension	(n = 158)	(n = 161)	2.7 (− 7 to 12)		.67
Yes	37 (23.4)	41 (25.5)			
No	121 (76.6)	120 (25.5)			
Intrusive memories just before hospital admission	(n = 158)	(n = 161)	−2 (−12 to 8)		.67
Yes	38 (24.1)	42 (26.1)			
No	120 (75.9)	119 (73.9)			
Discussion of ICU with family member	(n = 158)	(n = 161)	−2 (−10 to 7)		.71
Yes	131 (82.9)	136 (84.5)			
No	27 (17.1)	25 (15.5)			

(continued)

Table 2. Patient Outcomes at 3-Month Follow-up in a Study of the Effect of an Intensive Care Unit (ICU) Diary on Posttraumatic Stress Disorder Symptoms Among Patients Receiving Mechanical Ventilation (continued)

Outcomes	No. (%)		Risk Difference, % (95% CI)[a]	Difference (95% CI)[a]	*P* Value
	Intervention Group	Control Group			
Discussion of ICU with friend	(n = 158)	(n = 161)	−5 (−16 to 7)		.41
Yes	87 (55.1)	96 (59.9)			
No	71 (44.9)	65 (40.4)			
Discussion of ICU with nurse on the ward	(n = 158)	(n = 161)	−3 (−13 to 8)		.50
Yes	58 (36.7)	65 (40.4)			
No	100 (60.3)	96 (59.6)			
Discussion of ICU with physician of the ward	(n = 158)	(n = 161)	−4 (−14 to 7)		.47
Yes	48 (30.4)	55 (34.2)			
No	110 (69.6)	106 (65.8)			
Discussion of ICU with family physician	(n = 158)	(n = 161)	−2 (−13 to 9)		.86
Yes	75 (47.5)	78 (48.4)			
No	83 (52.5)	83 (51.6)			

Abbreviations: HADS, Hospital Anxiety Depression Scale; IES-R, Impact of Event Scale-Revised; IQR, interquartile range; PTSD, posttraumatic stress disorder.

[a] Risk difference and difference were not adjusted and correspond to intervention minus control.

[b] Measured using the IES-R score (overall range, 0-88; intrusion range: 0-32; avoidance range: 0-28; hyperarousal range: 0-24; a higher score indicates more severe symptoms).[17]

[c] Measured using the HADS score (overall range, 0-42; range for anxiety and depression subscales, 0-21; a higher score indicate more severe symptoms).

[d] Recollection of memories of the ICU stay was evaluated with the ICU memory tool questionnaire[21] 3 months after ICU discharge. The memory tool questionnaire asked patients about specific factual (faces, family, alarms, voices, lights, darkness, clock, breathing tube, suctioning, tube in nose, and wards rounds), emotional (panic, pain, being uncomfortable, feeling confused, feeling anxious or frightened, and feeling down) or delusional (dreams, nightmares, hallucinations, and someone trying to harm) memories.

Table 3. Secondary Outcomes in Families at 3-Month Follow-up in a Study of the Effect of an Intensive Care Unit (ICU) Diary on Posttraumatic Stress Disorder Symptoms Among Patients Receiving Mechanical Ventilation

Symptoms	Median (IQR)		Risk Difference (95% CI), %[a]	Difference (95% CI)[a]	*P* Value
	Intervention Group	Control Group			
PTSD[b]	**(n = 281)**	**(n = 282)**			
Presence of PTSD symptoms (IES-R score >22), No (%)	134 (47.7)	127 (45)	3 (−6 to 11)		.53
IES-R score	20 (11-35)	20 (10-37)		0.48 (−2.51 to 3.47)	.87
Intrusion score	10 (5-16)	10 (5-16)		0.15 (−1.08 to 1.37)	.87
Avoidance score	6 (2-11)	5 (2-11)		0.14 (−0.91 to 1.20)	.72
Hyperarousal score	3 (1-8)	3 (1-8)		0.17 (−0.76 to 1.12)	.99
Anxiety and Depression[c]	**(n = 286)**	**(n = 286)**			
HADS score	14 (9-20)	14 (9-22)		0.33 (−0.96 to 1.63)	.45
HADS-Anxiety score	7 (5-11)	7 (5-11)		0.28 (−0.47 to 1.04)	.65
HADS-Depression score	4 (1-7)	4 (1-7)		0.05 (−0.67 to 0.78)	.96
Presence of anxiety (HADS-Anxiety score >8), No. (%)	141 (49.3)	134 (46.9)	2 (−6 to 11)		.56
Presence of depression (HADS-Depression score >8), No. (%)	70 (24.5)	67 (23.4)	1 (−6 to 8)		.77

Abbreviations: HADS, Hospital Anxiety and Depression Scale; IES-R, Impact of Event Scale-Revised; IQR, interquartile range; PTSD, posttraumatic stress disorder.

[a] Not adjusted and correspond to the difference between the intervention minus the control.

[b] Measured using the IES-R score (overall range, 0-88; intrusion range: 0-32; avoidance range: 0-28; hyperarousal range: 0-24; a higher score indicates more severe symptoms).[17]

[c] Measured using the HADS score (overall range, 0-42; range for anxiety and depression subscales, 0-21; a higher score indicates more severe symptoms).

group (risk difference, 0.7% [95% CI, −9% to 11%]; *P* = .91). Symptoms of depression were reported in 31 patients (19%) in the intervention group vs 41 (23.7%) in the control group (risk difference, 5% [95% CI, −5% to 13%]; *P* = .35). The median (IQR) HADS anxiety scores were 5 (2-8) in the intervention group vs 6 (2-8) in the control group (difference, −0.36 [95% CI, −1.22 to 0.50]; *P* = .72). The median (IQR) HADS depression scores were 4 (1-7) in the intervention group vs 3 (2-7) in the control groups (difference, −0.39 [95% CI, −1.29 to 0.52]; *P* = .66; Table 2).

The memories of the ICU stay that were reported by patients were not different between the groups (Table 2). Unexplained episodes of panic occurred in 37 patients (23.4%) in the intervention group vs 41 (25.5%) in the control group (risk difference, 2.7% [95% CI, −7% to 12%]; *P* = .67). In the intervention group, 106 of 158 patients (67.1%) experienced

Table 4. Multivariable Analysis of the Occurrence of Posttraumatic Stress Disorder (PTSD) Symptoms Among Patients Receiving Mechanical Ventilation in the Intensive Care Unit (ICU) In a Study of the Effect of an ICU Diary[a]

	IES-R Score		Presence of PTSD Symptoms (IES-R Score >22)	
Variables	Rate Ratio (95% CI)	*P* Value	Odds Ratio (95%CI)	*P* Value
Intervention group	0.94 (0.78-1.13)	.52[b]	0.92 (0.54-1.54)	.75
Age, y		.02		
<52	1.19 (0.9-1.57)			
52-62	0.97 (0.73-1.27)			
63-70	0.78 (0.59-1.03)			
>70	1			
Female sex	1.21 (1-1.47)	.06	2.29 (1.33-3.91)	.002
Unexpected cardiac arrest	1.65 (1.06-2.57)	.03		
Memories[c]				
Emotional	1.39 (1.09-1.79)	.009		
Delusional	1.4 (1.12-1.74)	.003	3.54 (1.92-6.50)	<.001

Abbreviations: IES-R, Impact of Event Scale-Revised.

[a] Posttraumatic stress disorder symptoms were defined by an IES-R score >22 (range, 0-88; higher score indicates more severe symptoms).[17]

[b] Variables in the patient multivariable analysis included presence of a diary (forced variable), age, Simplified Acute Physiology Score II, sex, duration of benzodiazepine and fentanyl exposure, weaning failure and re-intubation, delirium, and emotional and delusional memories, on the basis of a *P* value threshold of <.20. Variables were further excluded to select the multivariable model, which minimized the log likelihood. For IES-R score, the association measure is the result of the negative binomial regression as the estimated rate ratio with its 95% CI and corresponds to the effect of each factor on the IES-R score For example, the intervention group compared with the control group, while holding the other variables constant in the model, is expected to have an IES-R score 0.94 times lower. This comparison is nonsignificant. For binary value of the IES-R score, the association measure is the odds ratio with its 95% CI.

[c] Recollection of the memories of the ICU stay was evaluated with the ICU memory tool questionnaire[21] 3 months after ICU discharge. The memory tool questionnaire asked patients about specific factual (faces, family, alarms, voices, lights, darkness, clock, breathing tube, suctioning, tube in nose, and wards rounds), emotional (panic, pain, being uncomfortable, feeling confused, feeling anxious or frightened, and feeling down), or delusional (dreams, nightmares, hallucinations, and someone trying to harm) memories.

delusional memories vs 108 of 161 (67.1%) in the control group. Emotional memories were reported by 119 patients (75.3%) in the intervention group vs 127 (78.9%) in the control group (risk difference, 4% [95% CI, −6% to 13%]; *P* = .45).

The number of family members with an IES-R score greater than 22 was 134 of 281 (47.7%) in the intervention group vs 127 of 282 (45%) in the control group (risk difference, 3% [95% CI −6% to 11%]; *P* = .53). The median IES-R score of family members was 20 in both groups. There was not a significant between-group difference in anxiety and depression symptoms in family members (Table 3).

Of the 325 ICU diaries, a random sample of 66 diaries (20%) were photocopied at patient discharge. Of the 66 diaries, 20 were unreadable and 46 were eligible for the content analysis, which included 979 pages (median per diary, 13.5 [95% CI, 7-21]), 518 days (median per diary, 9.5 [95% CI, 5.2-12]), and 8888 meaningful segments (median per diary, 156 [95% CI, 86.2-282.5]). Of the 8888 meaningful segments of text, 4563 (51.3%) were written by family members, 3022 (34%) were written by nurses and nursing assistants, and 1303 (14.7%) were written by physicians. Of the 4322 meaningful segments written by clinicians, 2048 (47.4%) were category 2 (building a timeline of medical events), 798 (18.5%) were category 6 (explicitly demonstrating the presence, commitment, and support of clinicians and family), 602 (13.9%) were category 4 (demonstrating continuity of the patient's life), and 389 (9%) were category 1 (defining places, spaces, and people) (eTable 6, eTable 7, eFigure 1, and eFigure 2 in Supplement 3).

Univariable and multivariable analysis assessing the risk factors of the increase of the IES-R score to greater than 22 in patients were reported in eTable 8 in Supplement 3 and **Table 4**. The occurrence of an unexpected cardiac arrest, emotional memories, and delusional memories of the ICU stay were significantly associated with an IES-R score greater than 22.

Adverse Events

No study-related adverse events were reported in either group.

Post Hoc Analysis

The number of readings of the diary by the patient could be assessed in 106 of 164 patients (64.6%). The median (range) number of readings per patient was 3 (2-4) (eResults in Supplement 3). The evaluation of primary and secondary outcomes in families of deceased patients did not exhibit any significant differences between groups (eTable 9 in Supplement 3).

Discussion

This randomized clinical trial of patients undergoing mechanical ventilation did not identify any significant difference between use of an ICU diary vs usual ICU care on the percentage of patients who reported PTSD symptoms. In addition, no significant between-group differences were found in any of the prespecified secondary outcomes. These results suggest that an ICU diary did not modify the psychological consequences of an ICU stay.

Improving post-ICU mortality is relevant for the most severely ill patients in the ICU. A systematic qualitative review suggested that it could be beneficial to address risk factors for

PTSD symptoms early during the ICU stay.[25] The results of the current trial differ from results of previous randomized studies.[9,26] In a study with an unblinded outcome assessment, a diary and a psychoeducation program reduced depression and posttraumatic symptoms 3 months after ICU discharge.[26] Patients with more severe PTSD symptoms 1 month after ICU discharge (post hoc analysis) had a reduction of PTSD symptoms at 3 months.[9]

There are 4 possible explanations for the failure of the intervention used in this trial to prevent or reduce PTSD symptoms in patients. First, patients read their diary a median of 3 times, which was less than previously reported.[27] Second, the delivery of the ICU diary may have been suboptimal if not performed during a formal meeting. Third, reading the ICU diary can be stressful, yielding a negative emotional experience for some patients. Fourth, although the PTSD rate was in the middle range of the prevalence of PTSD in survivors of critical illness,[6] the current study was not focused on high-risk patients, who may have different needs. Numerous preventive strategies have been evaluated to improve post-ICU morbidity.[22,28-30] Delivery of emotional support and coping strategies from a psychologist[28]; a rehabilitation manual containing advice on psychological, psychosocial, and physical problems[22]; and in-home telerehabilitation programs[29] were all inconclusive regarding their effect on patients after ICU discharge. A study of the effect of telephone and web-based coping skill training programs showed improved symptoms of distress among survivors of critical illness with high anxiety and depression symptoms at baseline.[30] The current trial adds insight to design studies to evaluate the diary in specific groups of patients, such as patients with trauma or severe PTSD symptoms at baseline.

The current trial also found that participation of families in the elaboration of ICU diaries did not modify their psychological outcomes. Qualitative evaluations have identified that ICUs diaries were useful during the ICU stay by helping families to assimilate and understand medical information, communicate with clinicians, and humanize the relationship with the patient or ICU team.[31] These positive intra-ICU effects did not affect long-term outcomes. The findings of the current trial are consistent with reports of programs found to be ineffective for preventing psychological symptoms, such as family communication facilitators during the ICU stay[32] or family support delivered by the ICU team.[33]

Grieving families experienced a considerable burden of harm.[7] In the current trial, grieving families received the ICU diary and there were no differences in their psychological outcomes, in contrast with other interventions previously examined (condolence letter), which may have worsened depression and PTSD symptoms in grieving family members.[34]

The strengths of this trial were the recruitment of patients from a large set of centers with patient characteristics that were consistent with characteristics of patients usually admitted to ICUs in France.[35] The analysis of content of the diaries, which indicated a high rate of participation of each contributor in writing a day-to-day event, showed that the intervention was delivered in all centers with a high reliability.

Limitations

This study had several limitations. First, symptoms of PTSD, anxiety, and depression were not evaluated at baseline in patients or family members. Second, completing an ICU diary is time-consuming[36] and some patients were not provided with a sufficiently detailed narrative of their stay in the diary, even if a recommendation for different clinical situations for ICU clinicians who completed the diaries tried to limit this phenomenon. Third, how patients and families shared the diary after ICU discharge was not assessed. Fourth, all the centers were in France so these results cannot be generalized to other countries. Fifth, the diary content analysis did not include all ICU diaries.

Conclusions

Among patients receiving mechanical ventilation in the ICU, the use of an ICU diary did not significantly reduce the percentage of patients who reported significant PTSD symptoms at 3 months. These findings do not support the use of ICU diaries for preventing PTSD symptoms.

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