

Supplementary Online Content

Garrouste-Orgeas M, Flahault C, Vinatier I, et al. Effect of an ICU diary on posttraumatic stress disorder symptoms among patients receiving mechanical ventilation: a randomized clinical trial. *JAMA*. doi:10.1001/jama.2019.9058

Supplement 2. Statistical analysis plan

This supplementary material has been provided by the authors to give readers additional information about their work.

Statistical Analysis Plan

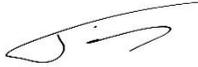
Version 1, Date: 12/09/2017

Title	ICU Diary
Référence PAS	PASICUdiaryV1
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1 - Changes history

All versions of this document are reported in the table below:

Version	Author	Description des modifications	Date
V1	Sébastien Bailly	First generation	12/09/2017

2 - Definitions

IES-R: Impact Event Scale-Revised.

HADS: Hospital Anxiety and Depression Scale.

PTSD: Post-traumatic stress-related syndrome.

3 - Objectives

3.1 Primary Endpoint

To evaluate the effectiveness of ICU diaries for patients and families in the post-traumatic stress-related syndrome in patients 3 months after ICU discharge as measured by the IES-R.

3.2 Secondary Endpoints

-The PTSD in families 3 months after ICU discharge, using the IES-R scale. The criteria of measurement will be the score of PTSD as having a low or high IES-R score, using 22 as the cutoff, as previously used in ICU studies.

-The anxiety and depression symptoms in patients 3 months after ICU discharge

-The anxiety and depression symptoms families 3 months after ICU discharge. Symptoms of anxiety and depression are assessed using the validated French version of the self-administered Hospital Anxiety and Depression Scale (HADS), which has seven items on anxiety and seven on depression. The sum for each domain ranges from 0 to 21. A score at 7 or below is considered normal. The cutoff score of 8 for each of the two subscales defines severe symptoms of anxiety or depression.

-The recollection of memories of the ICU stay by the patient 3 months after ICU discharge, as measured by the ICU Memory Tool Questionnaire. The ICU Memory Tool Questionnaire consists of items exploring recollections of the patient before and during their ICU stay. It also includes two questions to assess if PTSD symptoms are present. As no French version exists, the ICU memory tool questionnaire was translated and back-translated into French by bilingual researchers, namely a French native who speaks English and an English native who speaks French

-Diary content analysis. The content of a random sample of the study diaries will be analyzed with a grid which was built with a panel comprising 11 members (three ICU physicians including two from other units, one ICU nurse, two psychologists, two hospital visiting volunteers, one person from the general population with a history of admission

to another ICU, one former patient of our ICU, and his wife) using a Delphi technique. Six categories were defined and will serve for the analysis of the content of the diaries. We will report quantitatively the categories and themes which are represented most often in the diaries and will give verbatim examples for each of them.

-The way the patient uses the diary will be explored through a qualitative approach, analysing semidirective interviews with the patients of the intervention arm, performed 6 months after the ICU discharge using thematic and interpretative phenomenological analysis.

3.3 Hypothesis

3.3.1 Sample size calculation

Post-traumatic stress-related syndrome was reported in 15%, 20.7%, 51%, and 64% of patients and in 29.8%, 42%, 49% and 67% of family members of ICU patients. We hypothesized that patient's PTSD rate will be 40% in the control group and 26% in the intervention group. To detect such a difference between the two groups with a type 1 error of 0.05 and a power of 80%, it is necessary to interview 352 patients (176 in each group) at three months. At 3 month, considering a mortality rate of 40% and a cumulative rate of 50% of re-hospitalization or impossibility of interviewing the patient (refusal, sequalae or impossibility to join them), we will include 700 patients and their family member in the 35 centers. In each center, 20 patients will be included (10 in the intervention arm, i.e., with an ICU diary, and 10 in the control arm).

4 - Project Design

The ICU-Diary study is a prospective, multicenter, randomized, parallel (allocation ratio 1:1), and controlled study. The study was not blinded for the ICU staff but assessment was blinded for the psychologist processing the follow-up.

4.1 Inclusion criteria

- Age \geq 18 years old
- Mechanical ventilation for more than 48 hours and initiated within the first 48 hours after ICU admission.
- Patient having a family member speaking and understanding French, and susceptible to visit him during the ICU stay.
- Subject consenting to participate in the study, or obtention of the family consent in case of patient's incompetency.

4.2 Exclusion criteria

- Patient without family available.
- Patient or family not speaking or understanding French.
- Current or previously neurologic conditions that would preclude questionnaire completion such as pre-existing psychotic or dementia illness, hospitalization after a cardiac arrest, acute neurologic diseases (meningitis, ischemic or hemorrhagic stroke), or cerebral trauma patients.
- Patients status considered by the investigator to inevitably leading to death or to withdrawal of life support within 48 hours.
- Patient already included in a study with interview follow-up.

105 -Patient deprived of liberty.

106 -Deaf and mute patients.

107 4.3 Randomization

108 The 1:1 randomization is stratified by center and balanced with permutation blocks. Randomization is performed via
109 a secure and dedicated website managed by the ICUREsearch company. Family members or patients are randomized
110 at 48 h after ICU admission if they fulfill all inclusion and non-inclusion criteria.

111 5 - Measured variables retained for the analysis

112 Table CRF

	Variables	Format	Description
1	Centre	Integer	Center ID
2	Patient	Integer	Patient ID
3	Sexe	String (M/F)	Sex
4	Age	Integer	Age in years
5	Journal	Boolean (0/1)	1=ICU diary group ; 0=control group
6	Date d'admission en Réa	Date	ICU admission date
7	Date de sortie de Réa	Date	ICU discharge data
8	Statut vital en sortie de réa	Integer	ICU discharge vital status : 0=Dead ; 1=Alive
9	Date de sortie d'hospital	Date	Hospital discharge date
10	Statut vital en sortie d'hospital	Integer	Hospital discharge vital status : 0=Dead ; 1=Alive ;
11	Statut vital à M3	Integer	3 months vital status : 0=Dead ; 1=Alive ; 2=lost of follow up
12	Entretien à 3 mois	Integer	3 months interview : 0=NA ; 1=Accepted ; 2=Refused ; 3=Unable to participate ; 4= lost of follow up
13	Diagnostic principal	Integer	Type patient : 1=Medical ; 2=Scheduled surgery ; 3=Urgent surgery ; 4=Missed
14	Diagnostic d'admission	Integer	Principal diagnostic admission : 1=Acute respiratory distress ; 2=Acute renal failure ; 3=metabolic ; 4=Schudeled surgery ; 5=Septic shock ; 6=Coma ; 7=COPD ; 8=Multi-visceral failure ; 9=Trauma ; 10=Monitoring ; 11=Cardiogenic shock ; 12=Hemorrhagic shock ; 13=Missed
15	Score Knauss	Integer	Knauss score
16	Score Mac Cabe	Integer	Mac Cabe score
17	SAPS II	Integer	SAPSII score
18	Ventilation mécanique	Integer	Number of days of mechanical ventilation
19	Ventilation non invasive	Integer	Number of days of non invasive ventilation
20	Durée de traitement par Benzodiazépines	Integer	Number of days of treatment with benzodiazepine
21	Durée de traitement par Morphiniques	Integer	Number of days of treatment with morphinique
22	Durée de traitement par Propofol	Integer	Number of days of treatment with propofol
23	Auto-extubation	String	Self extubation : Oui=yes ; Non=no
24	Arret cardio-respiratoire	String	Heart failure : Oui=yes ; Non=no

25	Contention mécanique	String	Mechanical restraint : Oui=yes ; Non=no
26	Ré-intubation après échec de sevrage	String	Re-intubation after weaning failure : Oui=yes ; Non=no
27	Chute	String	Fall : Oui=yes ; Non=no
28	Agitation	String	Excitement : Oui=yes ; Non=no
29	Question	String	? : Oui=yes ; Non=no
30	Limitation / Arrêt des thérapeutiques	Integer	DNR : 0=No ; 1=Limitation ; 2=DNR ; 3=Limitation+DNR ; 4=Missed
31	Date Limitation des thérapeutiques	Date	Therapeutic Limitation date
32	Date Arrêt des thérapeutiques	Date	DNR date

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Table Patient

	Variables	Format	Description
1	Patient	Integer	Patient ID
2	Niveau d'étude	String	Bac+3 ; CAP, BEP ; Bac+5 ; Bac général, pro ; BTS ; Brevet des collèges ; none
3	Profession	Integer	1=Primary sector ; 2=Secondary sector ; 3=Tertiary sector ; 4=none ; 5=retired
4	PTSD_Q1 Any reminder brought back feelings about it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
5	PTSD_Q2 I had trouble staying asleep	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
6	PTSD_Q3 Other things kept making me think about it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
7	PTSD_Q4 I felt irritable and angry	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
8	PTSD_Q5 I avoided letting myself get upset when I thought about it or was reminded of it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
9	PTSD_Q6 I thought about it when it didn't mean to	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
10	PTSD_Q7 I felt as if it hadn't happened or wasn't real	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
11	PTSD_Q8 I stayed away from reminders of it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
12	PTSD_Q9 Pictures about it popped into my mind	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
13	PTSD_Q10 I was jumpy and easily startled	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
14	PTSD_Q11 I tried not to think about it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
15	PTSD_Q12 I was aware that I still had a lot of feelings about it, but I didn't deal with them	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely

16	PTSD_Q13 My feelings about it were kind of numb	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
17	PTSD_Q14 I found myself acting or feeling like I was back at that time	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
18	PTSD_Q15 I had trouble falling asleep	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
19	PTSD_Q16 I had waves of strong feelings about it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
20	PTSD_Q17 I tried to remove it from my memory	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
21	PTSD_Q18 I had trouble concentrating	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
22	PTSD_Q19 Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
23	PTSD_Q20 I had dreams about it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
24	PTSD_Q21 I felt watchful and on-guard	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
25	PTSD_Q22 I tried not to talk about it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
26	PTSD	Integer	IES-R score \geq 22
27	HAS_1 I feel tense or 'wound up'	Integer	0=Not at all ; 1=From time to time, occasionally ; 2=A lot of the time ; 3=Most of the time
28	HAS_2 I get a sort of frightened feeling as if something awful is about to happen	Integer	0=Not at all ; 1=A little, but it doesn't worry me ; 2=Yes, but not too badly ; 3=Very definitely and quite badly
29	HAS_3 Worrying thoughts go through my mind	Integer	0=Only occasionally ; 1=From time to time, but not too often ; 2=A lot of the time ; 3=A great deal of the time
30	HAS_4 I can sit at ease and feel relaxed	Integer	0=Definitely ; 1=Usually ; 2=Not Often ; 3=Not at all
31	HAS_5 I get a sort of frightened feeling like 'butterflies' in the stomach	Integer	0=Not at all ; 1=Occasionally ; 2=Quite Often ; 3=Very Often
32	HAS_6 I feel restless as I have to be on the move	Integer	0=Not at all ; 1=Not very much ; 2=Quite a lot ; 3=Very much indeed
33	HAS_7 I get sudden feelings of panic	Integer	0=Not at all ; 1=Not very often ; 2=Quite often ; 3=Very often indeed
34	HDS_1 I still enjoy the things I used to enjoy	Integer	0=Definitely as much ; 1=Not quite so much ; 2=Only a little ; 3=Hardly at all
35	HDS_2 I can laugh and see the funny side of things	Integer	0=As much as I always could ; 1=Not quite so much now ; 2=Definitely not so much now ; 3=Not at all

36	HDS_3 I feel cheerful	Integer	0=Most of the time ; 1=Sometimes ; 2=Not often ; 3=Not at all
37	HDS_4 I feel as if I am slowed down	Integer	0=Not at all ; 1=Sometimes ; 2=Very often ; 3=Nearly all the time
38	HDS_5 I have lost interest in my appearance	Integer	0=I take just as much care as ever ; 1=I may not take quite as much care ; 2=I don't take as much care as I should ; 3=Definitely
39	HDS_6 I look forward with enjoyment to things	Integer	0=As much as I ever did ; 1=Rather less than I used to ; 2=Definitely less than I used to ; 3=Hardly at all
40	HDS_7 I can enjoy a good book or radio or TV program	Integer	0=Often ; 1=Sometimes ; 2=Not often ; 3=Very seldom
41	Anxiety symptom	Integer	HAS \geq 8
42	Depression symptom	Integer	HDS \geq 8

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Table Family

	Variables	Format	Description
1	Patient	Integer	Patient ID
2	Family sex	String (M/F)	Sex of the family member
3	Family age	Integer	Age of the family member
4	Filiation	String	
5	Have you been hospitalized in an intensive care unit?	String	Oui=yes ; Non=no
6	Have you had a relative who was hospitalized in a resuscitation ward?	String	Oui=yes ; Non=no
7	Are you a health professional?	String	Oui=yes ; Non=no
8	Niveau d'étude	String	
9	Profession	Integer	1=Primary sector ; 2=Secondary sector ; 3=Tertiary sector ; 4=none ; 5=retired
10	PTSD_Q1 Any reminder brought back feelings about it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
11	PTSD_Q2 I had trouble staying asleep	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
12	PTSD_Q3 Other things kept making me think about it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
13	PTSD_Q4 I felt irritable and angry	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
14	PTSD_Q5 I avoided letting myself get upset when I thought about it or was reminded of it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
15	PTSD_Q6 I thought about it when it didn't mean to	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
16	PTSD_Q7 I felt as if it hadn't happened or wasn't real	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
17	PTSD_Q8 I stayed away from reminders of	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely

	it		
18	PTSD_Q9 Pictures about it popped into my mind	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
19	PTSD_Q10 I was jumpy and easily startled	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
20	PTSD_Q11 I tried not to think about it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
21	PTSD_Q12 I was aware that I still had a lot of feelings about it, but I didn't deal with them	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
22	PTSD_Q13 My feelings about it were kind of numb	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
23	PTSD_Q14 I found myself acting or feeling like I was back at that time	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
24	PTSD_Q15 I had trouble falling asleep	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
25	PTSD_Q16 I had waves of strong feelings about it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
26	PTSD_Q17 I tried to remove it from my memory	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
27	PTSD_Q18 I had trouble concentrating	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
28	PTSD_Q19 Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
29	PTSD_Q20 I had dreams about it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
30	PTSD_Q21 I felt watchful and on-guard	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
31	PTSD_Q22 I tried not to talk about it	Integer	0=Not at all ; 1=A little bit ; 2=Moderately ; 3=Quite a bit ; 4=Extremely
32	PTSD	Integer	IES-R score \geq 22
33	HAS_1 I feel tense or 'wound up'	Integer	0=Not at all ; 1=From time to time, occasionally ; 2=A lot of the time ; 3=Most of the time
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35	HAS_3 Worrying thoughts go through my mind	Integer	0=Only occasionally ; 1=From time to time, but not too often ; 2=A lot of the time ; 3=A great deal of the time
36	HAS_4 I can sit at ease and feel relaxed	Integer	0=Definitely ; 1=Usually ; 2=Not Often ; 3=Not at all
37	HAS_5	Integer	0=Not at all ; 1=Occasionally ; 2=Quite Often ;

	I get a sort of frightened feeling like 'butterflies' in the stomach		3=Very Often
38	HAS_6 I feel restless as I have to be on the move	Integer	0=Not at all ; 1=Not very much ; 2=Quite a lot ; 3=Very much indeed
39	HAS_7 I get sudden feelings of panic	Integer	0=Not at all ; 1=Not very often ; 2=Quite often ; 3=Very often indeed
40	HDS_1 I still enjoy the things I used to enjoy	Integer	0=Definitely as much ; 1=Not quite so much ; 2=Only a little ; 3=Hardly at all
41	HDS_2 I can laugh and see the funny side of things	Integer	0=As much as I always could ; 1=Not quite so much now ; 2=Definitely not so much now ; 3=Not at all
42	HDS_3 I feel cheerful	Integer	0=Most of the time ; 1=Sometimes ; 2=Not often ; 3=Not at all
43	HDS_4 I feel as if I am slowed down	Integer	0=Not at all ; 1=Sometimes ; 2=Very often ; 3=Nearly all the time
44	HDS_5 I have lost interest in my appearance	Integer	0=I take just as much care as ever ; 1=I may not take quite as much care ; 2=I don't take as much care as I should ; 3=Definitely
45	HDS_6 I look forward with enjoyment to things	Integer	0=As much as I ever did ; 1=Rather less than I used to ; 2=Definitely less than I used to ; 3=Hardly at all
46	HDS_7 I can enjoy a good book or radio or TV program	Integer	0=Often ; 1=Sometimes ; 2=Not often ; 3=Very seldom
47	Anxiety symptom	Integer	HAS \geq 8
48	Depression symptom	Integer	HDS \geq 8

6 - Statistical methods

6.1 Strategy of Statistical Analysis

The analysis will be done according to the intention-to-treat principle. In each randomization group, we will report summary statistics according to the data (median and interquartile range, percentage with a 95 % confidence interval). A proposition for descriptive table is presented in Annexes.

6.2 Methods of Analysis

6.2.1 Principal Analysis

A Mantel Haenszel chi square test will be used to assess the impact of ICU diaries on PTSD in patients. A generalized linear regression using a negative binomial distribution will be performed to adjust for confounding factors and to assess the impact of adjusted-ICU diaries effect on PTSD.

6.2.2 Secondary Analysis

- The same methods will be used to assess the impact of ICU diaries on PTSD in families.
- A logistic regression model will be performed to assess the determinant of high PTSD score for patient (>22). The same methods will be applied to the family's data.

- 129 - The same methods will be applied to assess anxiety and depression (Hospital Anxiety and Depression Scale)
130 for patients and families.
- 131 - The content of a random sample of the study diaries will be analyzed with a grid (Annexe 1) already
132 published. Six categories were defined and will serve for the analysis of the content of the diaries. We will
133 report quantitatively the categories and themes which are represented most often in the diaries and will
134 give examples of verbatim narratives for each of them.
- 135 - Qualitative analysis of patient interviews: these interviews will be conducted in the intervention arm and will
136 describe how the patient uses their diary. CV will conduct the patient interview by making direct phone calls.
137 Each interview will be audio-recorded, transcribed verbatim, and qualitatively analyzed to capture the
138 subjective use of the diary by the patient. A large sample of interviews will be subjected to the general
139 inductive approach while the others will be subjected to an interpretative phenomenological analysis in
140 order to understand in depth the meaning-making processes of the patients requiring intensive care.
- 141 - To explain the effect of patient state of health, family characteristics and patient PTSD on both anxiety and
142 depression, an exploration of direct and indirect effect of each variable on secondary outcomes will be
143 performed using mediation analysis based on a structural equation model. This approach consists of
144 distinguishing measured variables which are indicators of unmeasured (latent) variables and exogenous
145 variables which are exposure factors. Two steps will be performed: (1) an explanatory analysis to identify the
146 latent variables and their measures and (2) the confirmatory analysis to assess direct or indirect relations
147 between each latent variable. This second step is based on a conceptual model which clearly explains the
148 relations between latent variables and their measures and defines the pathway between latent variables.
149 Because PTSD, anxiety, and depression will all be measured by a score, this approach will be more relevant
150 to consider the different explicative factors. PTSD will be introduced as a latent variable to explain anxiety
151 and depression. Finally, the center effect could be considered by introducing a hierarchical level in the
152 mediation analysis. This point will be explored during the exploratory analysis.

153 6.3 Specific methods

154 6.3.1 Methods for handling missing data

155 Missing data analysis will be performed. Variables with less than 5% of missing values will be imputed by using
156 median for quantitative variables or the highest frequencies for qualitative variables. In the case where the percent of
157 missing data is higher than 5% and lower than 20% a multiple imputation method will be performed in the case
158 where missing are at random. In the case where missing values are not at random or if the percent of missing values
159 is higher than 20%, the variables will be excluded.

160 7 - Information systems, software and program validation

161 7.1 System & Software

162 All analyses will be performed using SAS® Version 9.4 (SAS Institute Inc., Cary, NC, USA) running Microsoft® Windows
163 10®. Graphic representations will be performed using R® Version 3.3.0.

165 **7.2 Validation of programs**

166 The statistician will be responsible for reviewing each program and the associated SAS® output. The SAS® "Journal"
167 will be examined for logical errors, syntax and fatal errors.

168 The results will be examined for typographical errors, misspellings and absurd values. The consistency of the results
169 will be examined

170

8 - Annexe 1 : Grid for the content analysis of the ICU diaries

Garrouste-Orgeas M, Coquet I, Perier A, et al. Crit Care Med. 2012;40(7):2033-2040

Category 1: Defining places, spaces, and people
Theme 1. Narrative about the ICU and its location in the hospital and city
Theme 2. Narrative about the identity and job responsibilities of each staff member
Theme 3. Narrative about the characteristics of the room
Theme 4. Narrative describing the photos posted in the room
Theme 5. Narrative about the characteristics and purpose of the machines
Theme 6. Narrative about the sights and sounds in the room
Theme 7. Narrative about the presence of, or visits by, members of the clergy
Category 2: Building a time-line of medical events
Theme 1. Narrative about the patient's history before ICU admission and after the first urgent interventions
Theme 2. Narrative about the condition of the patient, clinical course, treatments, procedures, investigations, and surgeries
Theme 3. Description of events that interfered or might have interfered with the presence of staff members at the bedside
Theme 4. Comments on life expectancy and the impact of the disorders on quality of life
Theme 5. Narrative describing exchanges among healthcare professionals involved with the patient: time-line and content
Theme 6. Narrative about the differences in tasks carried out by the day staff and night staff, to explain how the 24-hour cycle unfolds
Category 3: To replace the time-line of the patient's experience within the time-line of family, community, and world events
Theme 1. Narrative about events in the patient's personal life (narrator, family, friends ...)
Theme 2. Narrative about the difference in the perceived flow of events between the patient since ICU admission and the narrator or family/friends
Theme 3. Narrative about future projects for the patient
Theme 4. Narrative about social, political, economic, and cultural events
Theme 5. Narrative about the visits, their sequence in time, their duration, and factors that prevented some visits from occurring
Category 4: To demonstrate the continuity of the patient's life
Theme 1. Narrative about the patient's recent or remote past, habits, reactions, and personality traits
Theme 2. Narrative about the patient's behaviors, attitudes, and actions
Theme 3. Narrative about physical changes and attitudes (e.g., ability to open/close the eyes)
Theme 4. Narrative about changes in expressions of pain and responses to nursing care
Theme 5. Narrative about the patient's emotional responses to the voices of the staff and family/friends (smiling, small movements of the eyelids or body)
Theme 6. Narrative about the patient's emotional responses to physical contact (stroking, holding hands, touching...)
Category 5: To express feelings and emotions
Theme 1. Narrative that explicitly describes feelings or emotions about the patient

Theme 2. Narrative that explicitly describes feelings or emotions about or toward the staff
Theme 3. Narrative that explicitly describes feelings or emotions for family members or other loved ones
Theme 4. Narrative describing expectations, fears, discouragement, and hopes of the family and other loved ones
Theme 5. Narrative describing the fears and hopes of the staff
Category 6: To explicitly demonstrate the presence, commitment, and support of staff and family
Theme 1. To write an account of one's presence at the patient's bedside
Theme 2. To make one's presence felt in a personal and original way (poems, songs, music, drawings ...)
Theme 3. To describe relations between the patient and others while encouraging others to speak to, and to touch, the patient, despite the unfavorable environment
Theme 4. To describe one's physical involvement in communicating with the patient
Theme 5. To describe or refer to one's support in the form of prayers or any other religious or spiritual activity

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9 - Annexe 2 : Descriptive tables

9.1 Description of patient's characteristics

Variable name	Items	No diary	Diary	Missing	P value
age, median (IQR)					
Sexe					
Scolarity					
Profession					

9.2 Diagnosis and scores at ICU admission

Variable name	Items	No diary	Diary	Missing	P value
Type of ICU admission					
Diagnosis at ICU admission					
Knauss score					
SAPS II, median (IQR)					
Score MacCabe					

9.3 Observation during the ICU stay

Variable name	No diary	Diary	Missing	P value
Number of day of mechanical ventilation				
Number of days of non invasive ventilation				
Number of days with benzodiazepine administration,				
Number of days with morphine				
Number of days with propofol				
Automatic extubation				
Cardiac failure				
contention_meca				
Patient fall				
Reintubation				
Agitation patient				
ICU duration (days), median (IQR)				
Hospital duration from ICU admission, median (IAR)				
ICU death				
In-hospital death				

183 9.4 IER-S score – Primary objective

Variable name	Items	No diary	Diary	Missing	P value
score_PTSD, median (IQR)					
PTSD					
IERS SCORE ITEM Q1					
IERS SCORE ITEM Q2					
IERS SCORE ITEM Q3					
IERS SCORE ITEM Q4					
IERS SCORE ITEM Q5					
IERS SCORE ITEM Q6					
IERS SCORE ITEM Q7					
IERS SCORE ITEM Q8					
IERS SCORE ITEM Q10					
IERS SCORE ITEM Q11					
IERS SCORE ITEM Q12					
IERS SCORE ITEM Q13					
IERS SCORE ITEM Q14					
IERS SCORE ITEM Q15					
IERS SCORE ITEM Q16					
IERS SCORE ITEM Q17					
IERS SCORE ITEM Q18					
IERS SCORE ITEM Q19					
IERS SCORE ITEM Q20					
IERS SCORE ITEM Q21					
IERS SCORE ITEM Q22					
Avoidance scale					
Intrusion scale					
Hypervigilance scale					

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185 9.5 HAS score

Variable name	Items	No diary	Diary	Missing	P value
score_HAS, median (IQR)					
score_HAS_complet					
HAS_1					
HAS_2					
HAS_3					
HAS_4					
HAS_5					
HAS_6					
HAS_7					
Anxiety_symptom					

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9.6 HDS score

Variable name	Items	No diary	Diary	Missing	P value
score_HDS, median (IQR)					
score_HDS_complet					
HDS_1					
HDS_2					
HDS_3					
HDS_4					
HDS_5					
HDS_6					
HDS_7					
Depression_symptom					

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