

***Effect of an ICU diary on post-traumatic stress disorder symptoms among patients receiving mechanical ventilation: a randomized clinical trial***

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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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## Conflicts of interests outside of the study work

- Board: Merck, Paratek, 3M, Astellas, Gilead, Bayer, Maat Pharma, Nabriva
- Symposium: Biomerieux, Merck, Pfizer
- Research grants: Astellas, 3M, Merck, Pfizer

# Background

ICUs hospitalization are stressful for patients and families

Specific psychological consequences are individualized: *Post Intensive Care Syndrome*

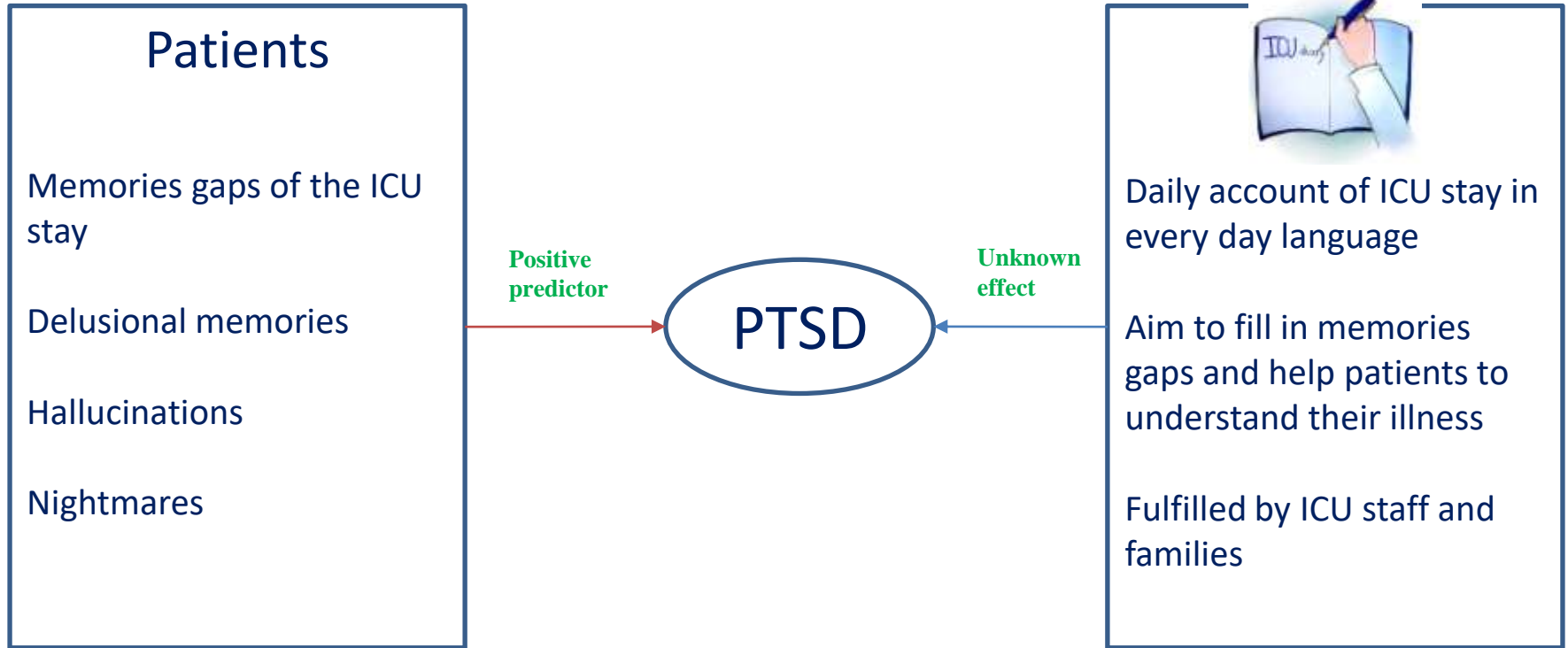
Survivors suffer of anxiety, depression and Post-traumatic Stress disorders (PTSD) symptoms

Families suffer of anxiety, depression, PTSD and complicated grief

## **Long term consequences of ICU hospitalization**

**→ Impaired quality of life**

*Pandharipande PP, NEJM 2013; Needham DM, CCM 2012; Azoulay E, CCM 2000; Adhikari NKJ, Chest 2009; Jones C, ICM 2004; Parker AM, CCM 2015; Kentish-Barnes N, Eur Respir L 2015; Jones C, CCM 2001*



# Objective

To assess the effect of an ICU diary on the occurrence of psychological consequences in patients and families in the ICU setting

# Design and setting

Assessor-blinded, multicenter (35 French ICUs), randomized CT

**Intervention group:** ICU diary opened at admission filled in by ICU staff and families members

**Control group:** Usual ICU care without ICU diary

Randomization: 1:1 ratio, stratified by center, secure web-base (block size 4)

# Study participants

## Inclusion criteria

**Adult patients** > 18-year old

**Mechanical ventilation**  $\geq$  48 hours

**Family member present at admission** and susceptible to **visit** the patient

**French language skills** for patient and families members

## Exclusion criteria

Preadmission diagnosis of **dementia, psychosis**

**Cardiac arrest** at admission

**Acute neurologic diseases** at admission

**Mute or deaf patients**

**Probable death or withdrawal of life support** within 48 hours of admission

# Intervention: *the ICU diary*

**Filled in by ICU staff and families in an every-day language**

**Writing guidelines for the ICU staff only**

*How to write down, Starting and continue with the ICU events, How to say a patient is not going well, How to conclude, How to deliver the diary?*

**Way of delivery:**

*Alive patient: the diary was detailed in the ICU room, a few days before discharge*

*Confused patient: the diary was given to the family member*

*Decedents: the diary was concluded with a condolence letter and mailed to the family*

# Study intervention: *adherence*

Educational meeting in each center promoted by the coordinating team

Monitoring of each diary by the local physician and nurse coordinators

Content analysis by 4 psychologists of a random sample of diaries

# Outcomes and measures

## Primary

PTSD symptoms in patients 3 months after ICU discharge: IES-R score > 22 (range 0-88)

## Prespecified secondary

- ◆ PTSD symptoms in **families** 3 months after ICU discharge: IES-R score > 22 (range 0-88)
- ◆ **Anxiety and Depression** symptoms in **patients and families** 3 months after ICU discharge (HAS, HAD > 8 (range 0-21)
- ◆ Recollection of **memories of patients 3 months** after ICU discharge: **Memory tool questionnaire**
- ◆ **Content analysis** of ICU diaries with a grid built with Delphi techniques by a panel of 11 members that described 6 categories.

## Post hoc secondary outcomes

- ◆ Number of times the patient reported reading the diary during an interview 6 months after ICU discharge
- ◆ PTSD, HAD, HAS in families of deceased patients

# Sample size

## Hypothesis:

PTSD rate 40% (control group) and 26% (intervention group)

Assuming a rate of 50% (re-hospitalization, mortality, unable to contact)

B= 0.2;  $\alpha$ = 0.05 bilateral

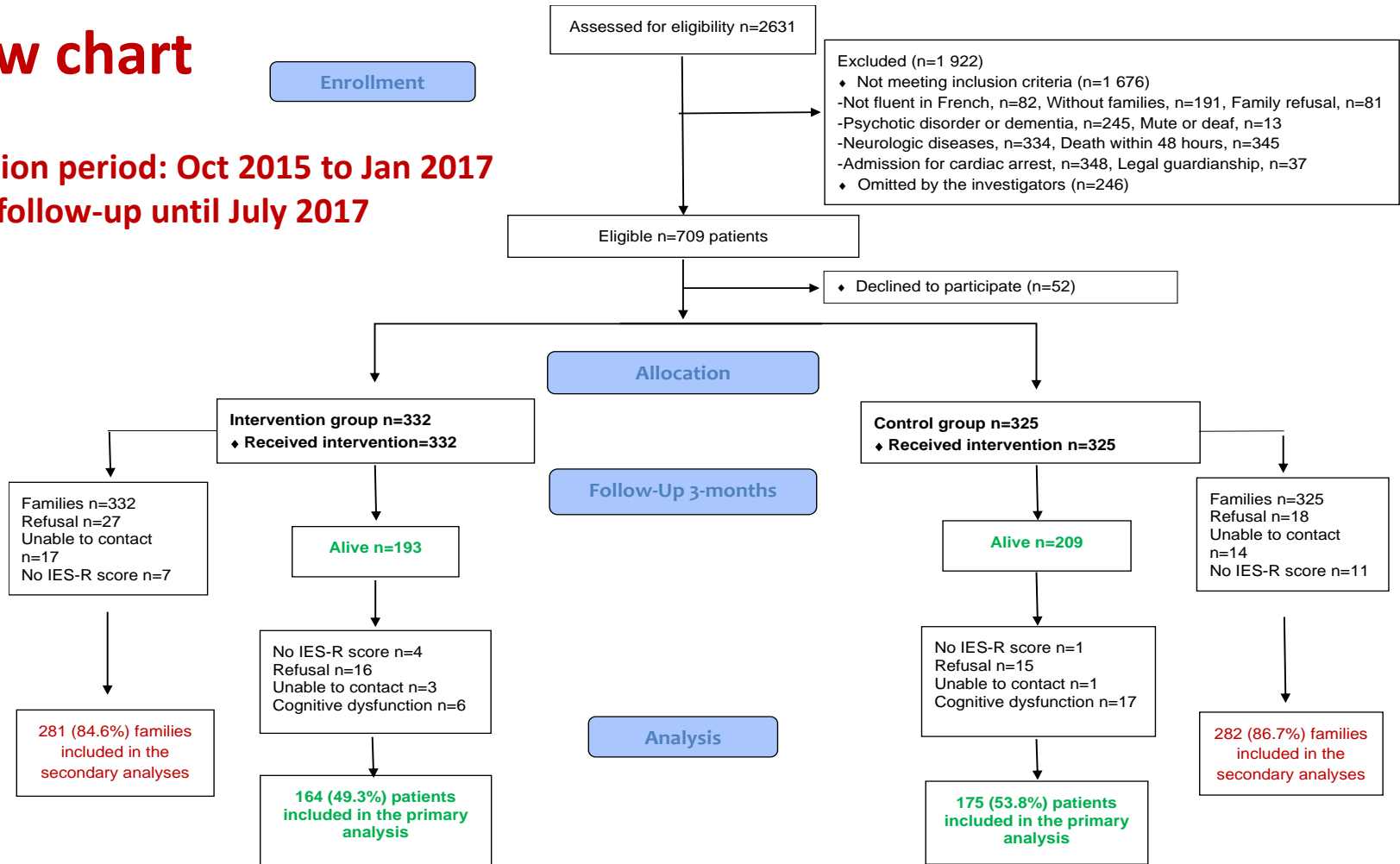
**700 patients in 35 centres**

to analyse **352 survivors** able to participate (**176 in each group**)

# Flow chart

Enrollment

Inclusion period: Oct 2015 to Jan 2017  
With follow-up until July 2017



# ICU characteristics

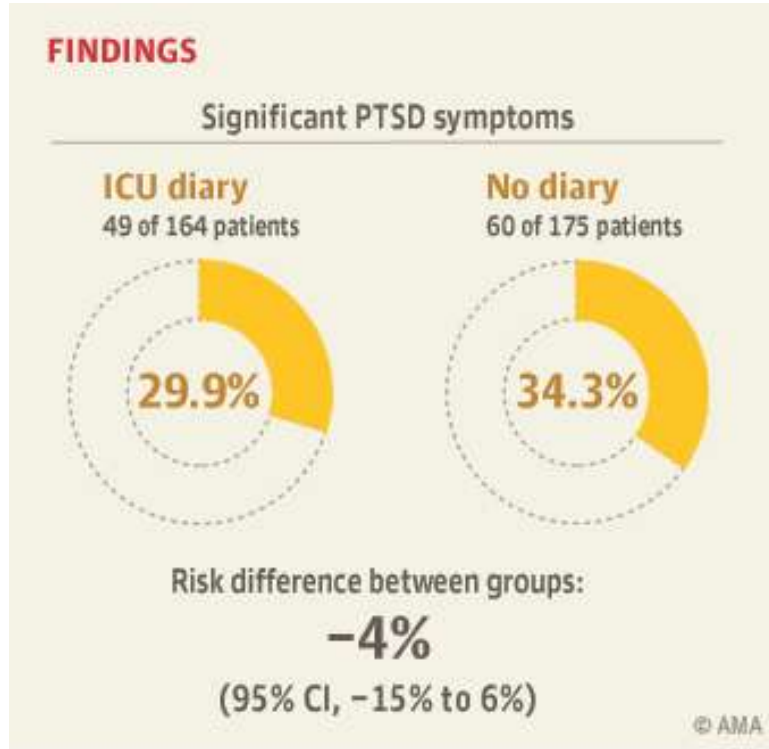
| Variables   | Data         |
|---|--------------|
| <b>Hospital</b>   |              |
| University hospital, N (%)                                  | 21 (60)      |
| <b>ICU</b>  |              |
| Medical, N (%)  | 12 (34.2)    |
| Surgical, N (%)   | 3 (8.6)      |
| Mixed, N (%)  | 20 (57.1)    |
| Number of acute beds per unit, median (IQR)                 | 14 (12-18)   |
| Number of intermediate beds per unit, median (IQR)          | 6 (4-8)      |
| Number of attending physicians, median (IQR)                | 7 (5.95-9.5) |
| Number of junior physicians, median (IQR)                   | 6 (5-8)      |
| Number of nurses, median (IQR)                              | 39 (35-53.4) |
| Number of nursing-assistants, median (IQR)                  | 24 (19-36.5) |
| Number of head nurses, median (IQR)                         | 2 (1-2)      |
| Availability of a psychologist N (%)                        | 8 (22.8)     |
| Patient-to-nurse ratio, median (IQR)                        | 2.5 (2.5-3)  |
| Patient-to-nursing-assistant ratio, median (IQR)            | 4 (4-4)      |
| 12-hour shifts for nurses <sup>a</sup> , N (%)              | 27 (77.1)    |
| 12-hours shifts for nursing-assistants <sup>a</sup> , N (%) | 25 (71.4)    |
| Number of ICUs offering daily visitation hours, N (%)       |              |
| < 5 hours   | 4 (11.4)     |
| ≤ 5 hours < 10  | 11 (31.4)    |
| ≤ 10 hours < 24   | 3 (8.6)      |
| 24 hours  | 17 (48.6)    |

# Patients and families characteristics

| Variables                               | Intervention Group | Control Group |
|---|--------------------|---------------|
|   | N=164              | N=175         |
| <b>Patients</b>                         |                    |               |
| <b>Demographics</b>                     |                    |               |
| Age, median (IQR), y                    | 62.5 (49.5-70)     | 61 (51-70)    |
| Male gender                             | 110 (67.1)         | 103 (58.9)    |
| <b>Severity of illness on admission</b> |                    |               |
| SAPS II , median (IQR)                  | 51.5 (38.5-66.5)   | 53 (39-66)    |
| <b>Patient status</b>                   |                    |               |
| Medical patients                        | 122 (74.4)         | 138 (78.9)    |
| <b>Main symptom at admission</b>        |                    |               |
| Acute respiratory failure/COPD)         | 75 (45.7)          | 84 (48)       |
| Shock and multi-organ failure           | 66 (40.2)          | 68 (38.8)     |
| <b>Treatment, days</b>                  |                    |               |
| Mechanical ventilation                  | 9 (6-15)           | 9 (5-15)      |
| Duration of ICU stay, days              | 14 (9-22)          | 14 (9-24)     |
| Duration of hospital stay, days         | 29 (16-49)         | 27 (17-45)    |

| Variables                            | Intervention Group<br>N=281 | Control Group<br>N=282 |
|--------------------------------------|-----------------------------|------------------------|
| <b>Families</b>                      |                             |                        |
| <b>Demographics</b>                  |                             |                        |
| Age, median (IQR), (N=538)           | 56.5 (45-66)                | 55 (44.5-66)           |
| Male gender                          | 73 (26)                     | 86 (30.5)              |
| <b>Relationship with the patient</b> |                             |                        |
| Spouse/partner                       | 156 (55.5)                  | 155 (55)               |
| <b>Job occupation</b>                | <b>N=274</b>                | <b>N=277</b>           |
| 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)              |
| <b>Educational level</b>             | <b>N=273</b>                | <b>N=272</b>           |
| 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)              |

# Outcomes in patients at 3 months of follow-up



<sup>a</sup> Risk difference and difference were not adjusted and correspond to intervention minus control

<sup>b</sup> 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)

# 3-month Outcomes (Patients)

| Variables                                    | No. (%)               |                  | Risk Difference <sup>a</sup><br>(95% CI) | Difference <sup>a</sup><br>(95% CI) | p-value |
|--|-----------------------|------------------|--|-------------------------------------|---------|
|  | Intervention<br>Group | Control<br>Group |  |                                     |         |
|  | N=164                 | N=175            |  |                                     |         |
| <b>Primary outcomes</b>                      |                       |                  |  |                                     |         |
| <b>Presence of PTSD<sup>b</sup> symptoms</b> | 49 (29.9)             | 60 (34.3)        | -4% (-15% to 6%)                         |                                     | 0.39    |
| <b>IES-R score<sup>b</sup>, median (IQR)</b> | 12 (5-25)             | 13 (6-27)        |  | -1.47 (-1.93 to 4.87)               | 0.38    |
| <b>PTSD symptoms, median (IQR)</b>           |                       |                  |  |                                     |         |
| <b>Intrusion</b>                             | 5 (2-9)               | 5 (2-11)         |  | -0.25 (-1.64 to 1.12))              | 0.74    |
| <b>Avoidance</b>                             | 4 (1-9.5)             | 5 (2-10)         |  | -1.01 (-2.35 to 0.33)               | 0.08    |
| <b>Hyperarousal</b>                          | 2 (0-6)               | 2 (0-5)          |  | -0.08 (-1.11 to 0.94)               | 0.64    |

<sup>a</sup> Risk difference and difference were not adjusted and correspond to intervention minus control

<sup>b</sup> 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)

# 3-month Secondary outcomes (Patients)

| Variables                       | No. (%)               |                  | Risk Difference<br>(95% CI) | Difference<br>(95% CI) | p-value |
|---------------------------------|-----------------------|------------------|-----------------------------|------------------------|---------|
|                                 | Intervention<br>Group | Control<br>Group |                             |                        |         |
|                                 | N=164                 | N=175            |                             |                        |         |
| <b>HADS</b>                     | N=163                 | N=173            |                             |                        |         |
| <b>HADS score, median (IQR)</b> | 9 (5-14)              | 9 (5-13)         |                             | -0.75 (-2.27 to 0.78)  | 0.30    |
| <b>HAS score, median (IQR)</b>  | 5 (2-8)               | 6 (2-8)          |                             | -0.36 (-1.22 to 0.50)  | 0.72    |
| <b>HAD score, median (IQR)</b>  | 4 (1-7)               | 3 (2-7)          |                             | -0.39 (-1.29 to 0.52)  | 0.66    |

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

# 3-month Secondary outcomes (Patients)

| Variables                                    | No. (%)               |                  | Risk Difference<br>(95% CI) | Difference<br>(95% CI) | p-value |
|--|-----------------------|------------------|-----------------------------|------------------------|---------|
|  | Intervention<br>Group | Control<br>Group |                             |                        |         |
|  | N=164                 | N=175            |                             |                        |         |
| <b>Memories of the ICU stay <sup>a</sup></b> | <b>N=158</b>          | <b>N=161</b>     |                             |                        |         |
| <b>Factual memories</b>                      | 141 (89.2)            | 143 (88.8)       | 0.4% (-7% to 8%)            |                        | 0.90    |
| <b>median (IQR)</b>                          | 5 (2-8)               | 6 (3-8)          |                             | -0.32 (-1.03 to 0.39)  | 0.44    |
| <b>Memories of sensations</b>                | 119 (75.3)            | 127 (78.9)       | 4% (-6% to 13%)             |                        | 0.45    |
| <b>median (IQR)</b>                          | 2 (1-4)               | 2 (1-4)          |                             | -0.15 (-0.58 to 0.27)  | 0.51    |
| <b>Delusional memories</b>                   | 106 (67.1)            | 108 (67.1)       | 0% (-11% to 11%)            |                        | >.99    |
| <b>median (IQR)</b>                          | 1 (0-2)               | 2 (0-2)          |                             | -0.07 (-0.35 to 0.22)  | 0.57    |

<sup>a</sup> 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

# 3-month Secondary outcomes (Families)

| Variables                             | No. (%)                        |                           | Risk difference <sup>a</sup><br>95% CI | Difference <sup>a</sup><br>95% CI | p-value |
|---------------------------------------|--------------------------------|---------------------------|--|-----------------------------------|---------|
|                                       | Intervention<br>Group<br>N=281 | Control<br>Group<br>N=282 |  |                                   |         |
| Presence of PTSD symptoms             | <b>134 (47.7)</b>              | <b>127 (45)</b>           | 3% (-6% to 11%)                        |                                   | 0.53    |
|                                       | <b>N=286</b>                   | <b>N=286</b>              |  |                                   |         |
| HADS score, median (IQR)              | 14 (9-20)                      | 14 (9-22)                 |  | 0.33 (-0.96 to 1.63)              | 0.45    |
| HAS score, median (IQR)               | 7 (5-11)                       | 7 (5-11)                  |  | 0.28 (-0.47 to 1.04)              | 0.65    |
| HADscore, median (IQR)                | 4 (1-7)                        | 4 (1-7)                   |  | 0.05 (-0.67 to 0.78)              | 0.96    |
| Anxiety symptoms in family members    | 141 (49.3)                     | 134 (46.9)                | 2% (-6% to 11%)                        |                                   | 0.56    |
| Depression symptoms in family members | 70 (24.5)                      | 67 (23.4)                 | 1% (-6% to 8%)                         |                                   | 0.77    |

<sup>a</sup> Risk difference and difference were not adjusted and correspond to intervention minus control

# Diaries characteristics of a random sample (n=46)

60 (20%) were reproduced

20 were unreadable and 46 were analysed

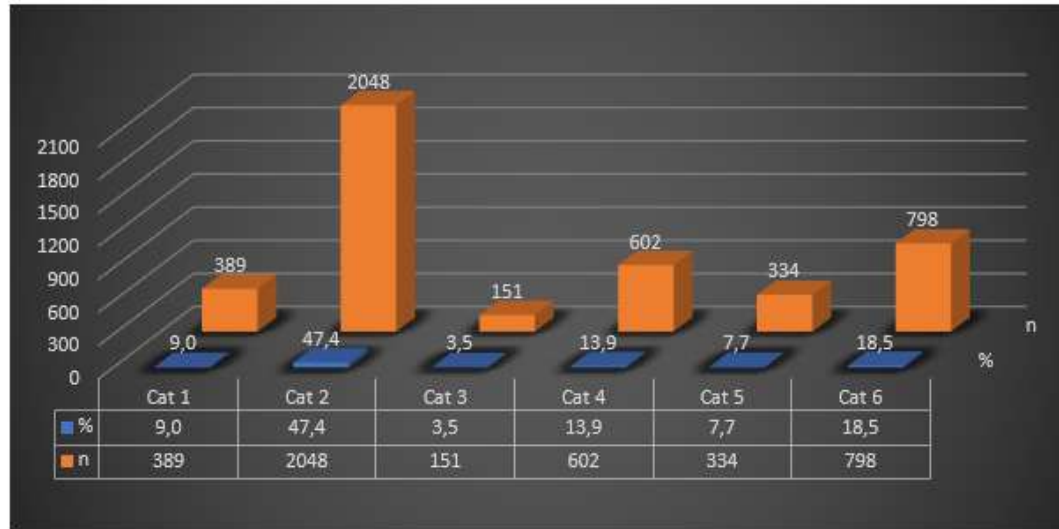
**Number of readings per patients at 6 months: median 3, range :2-4**

| Variables | N=46 diaries | Per diary | 95% CI |
|-----------|--------------|-----------|--------|
| Pages, n  | 979          | 13.5      | 7-21   |
| Days, n   | 518          | 9.5       | 5.2-12 |

| Variables                           | N    | Category    | N (%) in each category |
|-------------------------------------|------|-------------|------------------------|
| Meaningful segment<br>in 46 diaries | 8888 | Physicians  | 1303 (14,7%)           |
|                                     |      | Nurses, N/A | 3022 (34%)             |
|                                     |      | Families    | 4563 (51,3%)           |

The unit of analysis was the thematic segment. Each sentence or sequence of sentences was divided into meaningful segments

# Content analysis of ICU diaries: distribution of meaningful segments written by clinicians in a random sample of 46 diaries



4,322 meaningful segments were found in 6 categories.

**Category 1:** Defining places, spaces, and people

**Category 2:** Building a time-line of medical events

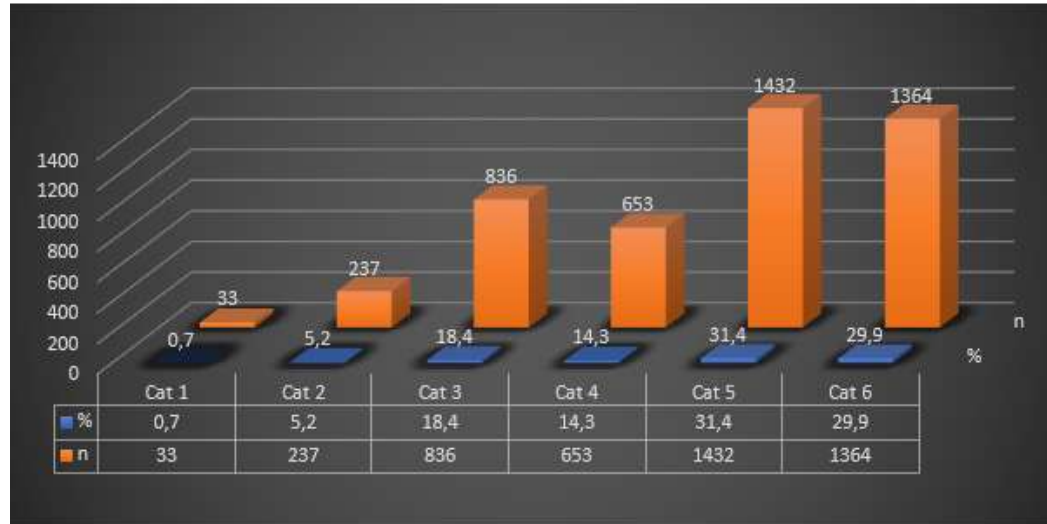
**Category 3:** To replace the time-line of the patient's experience within the time-line of family, community, and world events

**Category 4:** To demonstrate the continuity of the patient's life

**Category 5:** To express feelings and emotions

**Category 6:** To explicitly demonstrate the presence, commitment, and support of clinicians and family

# Content analysis of ICU diaries: distribution of meaningful segments written by families in a random sample of 46 diaries



4,322 meaningful segments were found in 6 categories.

**Category 1:** Defining places, spaces, and people

**Category 2:** Building a time-line of medical events

**Category 3:** To replace the time-line of the patient's experience within the time-line of family, community, and world events

**Category 4:** To demonstrate the continuity of the patient's life

**Category 5:** To express feelings and emotions

**Category 6:** To explicitly demonstrate the presence, commitment, and support of clinicians and family

## Strengths

**Recruitments of patients from a large set of centers**

**High participation of each contributor in writing a day-to-day events**

**Acceptable richness of diary content**

**High reliability of the intervention**

## Limitations

**No evaluation at baseline of outcomes (PTSD, HADS)**

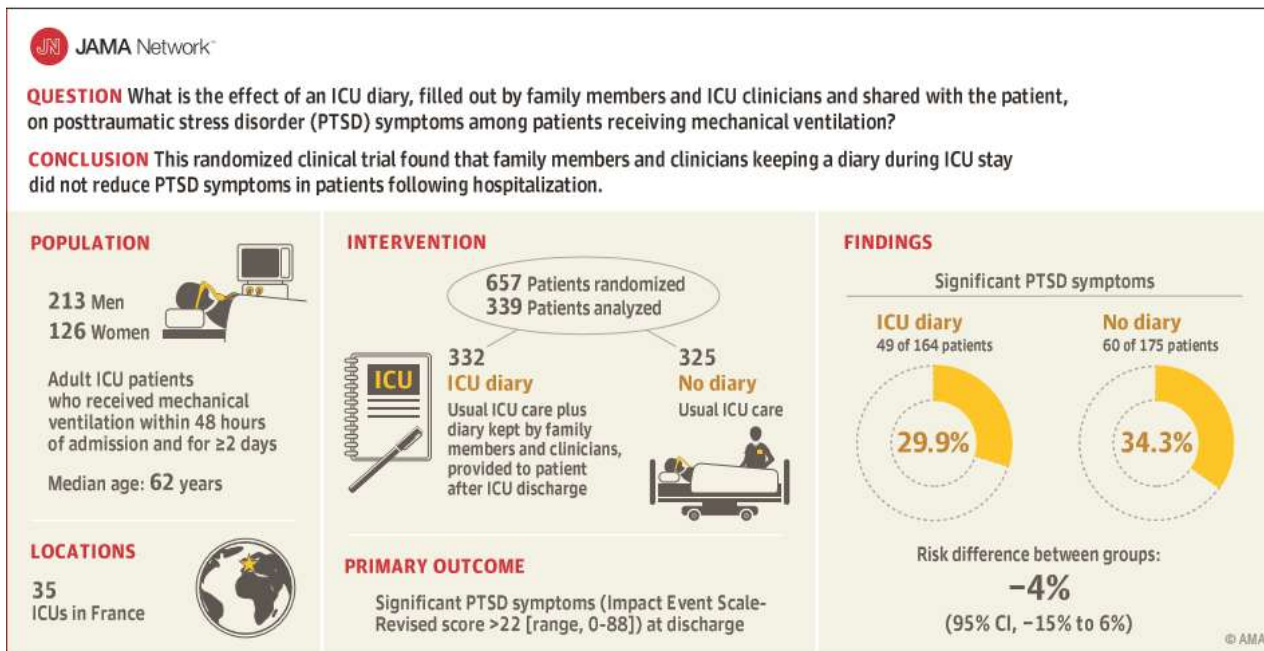
**Possible perception of patients of insufficient content**

**Distribution of the diary not linked to a postdischarge follow-up visit to provide context and support.**

**All centers located in France**

# Conclusions

**CONCLUSION** This randomized clinical trial found that family members and clinicians keeping a diary during ICU stay did not reduce PTSD symptoms in patients following hospitalization.



**Back up**

# Primary and secondary outcomes at 3 months in families of deceased patients

| Variables                               | No. (%)                        |                          | Risk difference <sup>a</sup><br>95% CI | Difference <sup>a</sup><br>95% CI | p-value |
|---|--------------------------------|--------------------------|--|-----------------------------------|---------|
|   | Intervention<br>Group<br>N=103 | Control<br>Group<br>N=79 |  |                                   |         |
| Presence of PTSD symptoms               | 68 (66)                        | 54 (68.4)                | 4% (-8% to 15%)                        |                                   | 0.74    |
| IES-R score , median (IQR)              | 29 (19-46)                     | 32 (19-46)               |  | 0.36 (-4.99 to 5.72)              | >.99    |
| Symptoms of PTSD, median (IQR)          |                                |                          |  |                                   |         |
| Intrusion                               | 15 (10-19)                     | 16 (10-21)               |  | -0.26 (-2.30 to 1.77)             | 0.68    |
| Avoidance                               | 8 (4-14)                       | 8 (4-14)                 |  | -0.01 (-2.03 to 2.01)             | 0.99    |
| Hyperarousal                            | 5 (2-12)                       | 5 (2-9)                  |  | 0.64 (-1.12 to 2.39)              | 0.82    |
| HADS score, median (IQR)                | 14 (9-20)                      | 14 (9-22)                |  | 1.02 (-1.23 to 3.64)              | 0.45    |
| HAS score, median (IQR)                 | 8 (5-13)                       | 7 (5-11)                 |  | 1.11 (-0.24 to 2.46)              | 0.18    |
| HAD score, median (IQR)                 | 6 (3-10)                       | 6 (4-10)                 |  | 0.10 (-1.25 to 1.45)              | 0.92    |
| Anxiety symptoms in family's members    | 59 (57.3)                      | 38 (48.7)                | 9% (-6% to 24%)                        |                                   | 0.25    |
| Depression symptoms in family's members | 68 (66)                        | 54 (68.4)                | 3% (-11% to 18%)                       |                                   | 0.66    |

<sup>a</sup> Risk difference and difference were not adjusted and correspond to intervention minus control

## Qualitative analysis of the number of meaningful segments in each category in a random sample of ICU diaries (n=46)

| Diary number | Category 1<br>N (%) | Category 2<br>N (%) | Category 3<br>N (%) | Category 4<br>N (%) | Category 5<br>N (%) | Category 6<br>N (%) | Meaningful segments<br>outside categories |
|--------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---|
| 1            | 6 (3,3)             | 40 (22,3)           | 8 (4,4)             | 36 (20,1)           | 42 (23,4)           | 47 (25,2)           | 0   |
| 2            | 1 (0,9)             | 20 (18,8)           | 3 (2,8)             | 11 (10,3)           | 37 (34,9)           | 34 (32,0)           | 0   |
| 3            | 0                   | 7 (46,6)            | 1 (6,6)             | 2 (13,3)            | 4 (26,6)            | 1 (6,6)             | 0   |
| 4            | 21 (5,7)            | 78 (21,4)           | 29 (7,8)            | 53 (14,6)           | 97 (26,6)           | 86 (23,6)           | 0   |
| 5            | 13 (7,2)            | 25 (13,9)           | 50 (27,9)           | 25 (13,8)           | 41 (22,9)           | 25 (14)             | 0   |
| 6            | 13 (7,0)            | 66 (35,7)           | 20 (10,8)           | 26 (14,0)           | 25 (13,5)           | 35 (18,9)           | 0   |
| 7            | 1 (1,9)             | 7 (13,5)            | 6 (11,5)            | 10 (19,2)           | 15 (28,8)           | 13 (25)             | 0   |
| 8            | 1 (3,1)             | 8 (25)              | 2 (6,2)             | 1 (3,1)             | 18 (56,2)           | 2 (6,2)             | 0   |
| 9            | 4 (1,8)             | 37 (17,3)           | 20 (9,3)            | 19 (8,9)            | 86 (40,1)           | 48 (22,4)           | 0   |
| 10           | 15 (3,5)            | 118 (28)            | 91 (21,6)           | 53 (12,5)           | 58 (13,7)           | 87 (20,6)           | 0   |
| 11           | 7 (8,5)             | 24 (29,3)           | 13 (15,9)           | 15 (18,3)           | 12 (14,6)           | 11 (13,4)           | 0   |
| 12           | 8 (6,7)             | 29 (24,1)           | 19 (15,8)           | 25 (20,8)           | 18 (15)             | 21 (17,5)           | 0   |
| 13           | 11 (3)              | 66 (17,8)           | 66 (17,8)           | 29 (7,8)            | 80 (21,6)           | 119 (32,0)          | 0   |
| 14           | 9 (3,0)             | 44 (15,1)           | 20 (6,9)            | 56 (19,2)           | 71 (24,3)           | 91 (31,3)           | 0   |
| 15           | 21 (5,5)            | 79 (21)             | 51 (13,4)           | 29 (7,6)            | 95 (25)             | 104 (27,4)          | 0   |
| 16           | 7 (5,1)             | 36 (26,3)           | 18 (13,1)           | 23 (16,8)           | 20 (14,6)           | 33 (24,0)           | 0   |
| 17           | 2 (1,1)             | 16 (8,8)            | 16 (8,8)            | 12 (6,6)            | 75 (41,4)           | 60 (33,1)           | 0   |
| 18           | 14 (3,6)            | 67 (17,0)           | 37 (9,4)            | 56 (14,3)           | 87 (22,2)           | 131 (44,9)          | 0   |
| 19           | 3 (4,4)             | 21 (30,9)           | 1 (1,5)             | 27 (39,8)           | 9 (13,2)            | 7 (10,3)            | 0   |
| 20           | 1 (1,8)             | 22 (39,3)           | 1 (1,8)             | 19 (34)             | 5 (9)               | 8 (14,3)            | 0   |
| 21           | 5 (12,5)            | 19 (47,5)           | 3 (7,5)             | 5 (12,5)            | 5 (12,5)            | 3 (7,5)             | 0   |
| 22           | 27 (7,8)            | 108 (31,1)          | 17 (4,5)            | 35 (10)             | 48 (13,9)           | 112 (32,3)          | 0   |
| 23           | 9 (3,1)             | 69 (24)             | 41 (14,2)           | 56 (19,5)           | 55 (19)             | 55 (19)             | 3   |
| 24           | 7 (7,1)             | 28 (28,3)           | 8 (8,1)             | 9 (9,1)             | 25 (25,2)           | 22 (22,2)           | 0   |
| 25           | 3 (2,9)             | 34 (33,7)           | 13 (12,9)           | 10 (9,9)            | 23 (22,8)           | 18 (17,9)           | 0   |
| 26           | 3 (7,1)             | 24 (57,1)           | 2 (4,8)             | 2 (4,8)             | 5 (12)              | 6 (14,3)            | 0   |
| 27           | 2 (5,1)             | 11 (28,2)           | 7 (18)              | 7 (18)              | 6 (15,4)            | 6 (15,4)            | 0   |
| 28           | 4 (8,3)             | 23 (48)             | 2 (4,2)             | 12 (25)             | 4 (8,3)             | 3 (6,3)             | 0   |
| 29           | 3 (2,4)             | 30 (24,2)           | 19 (15,3)           | 32 (25,8)           | 12 (9,7)            | 28 (22,6)           | 0   |
| 30           | 3 (5,7)             | 26 (49)             | 1 (1,9)             | 7 (13,2)            | 6 (11,3)            | 10 (18,8)           | 0   |
| 31           | 11 (5,3)            | 30 (14,4)           | 12 (5,8)            | 44 (21,2)           | 54 (26)             | 57 (27,4)           | 0   |
| 32           | 4 (2,5)             | 31 (19,8)           | 21 (13,4)           | 15 (9,6)            | 34 (21,7)           | 52 (33,1)           | 0   |
| 33           | 8 (3,5)             | 82 (36)             | 12 (5,3)            | 55 (24,1)           | 24 (10,5)           | 47 (20,7)           | 0   |
| 34           | 2 (0,8)             | 154 (57,9)          | 7 (2,6)             | 74 (27,9)           | 3 (1,1)             | 26 (9,8)            | 0   |
| 35           | 6 (5,9)             | 50 (48,5)           | 5 (4,9)             | 16 (15,5)           | 13 (12,6)           | 12 (11,6)           | 1   |
| 36           | 11 (4,6)            | 86 (36,3)           | 26 (11)             | 30 (12,7)           | 28 (11,9)           | 56 (23,6)           | 0   |
| 37           | 30 (5,1)            | 97 (16,4)           | 83 (14,1)           | 89 (15,1)           | 136 (23,1)          | 153 (26)            | 2   |
| 38           | 26 (5)              | 64 (12,1)           | 93 (17,5)           | 68 (12,9)           | 130 (24,5)          | 149 (28,1)          | 0   |
| 39           | 15 (8,9)            | 74 (43,5)           | 14 (8,2)            | 14 (8,2)            | 13 (7,6)            | 40 (23,5)           | 0   |
| 40           | 14 (4,6)            | 120 (39,1)          | 38 (12,4)           | 22 (7,2)            | 35 (11,4)           | 73 (23,8)           | 5   |
| 41           | 24 (5,4)            | 96 (21,7)           | 45 (10,1)           | 56 (12,6)           | 118 (26,6)          | 105 (23,6)          | 0   |
| 42           | 8 (5,3)             | 35 (23,3)           | 7 (4,7)             | 13 (8,7)            | 29 (19,3)           | 58 (38,7)           | 0   |
| 43           | 3 (2,0)             | 72 (50)             | 10 (6,8)            | 35 (24)             | 6 (4,1)             | 21 (14,3)           | 0   |
| 44           | 15 (9,7)            | 68 (43,9)           | 6 (3,9)             | 8 (5,2)             | 18 (11,7)           | 40 (25,9)           | 0   |
| 45           | 4 (9,1)             | 7 (16)              | 6 (13,7)            | 1 (2,3)             | 15 (34,1)           | 11 (25)             | 0   |
| 46           | 17 (11,7)           | 37 (25,3)           | 17 (11,7)           | 13 (9)              | 26 (17,9)           | 36 (24,7)           | 0   |

**Category 1:** Defining places, spaces, and people

**Category 2:** Building a time-line of medical events

**Category 3:** To replace the time-line of the patient's experience within the time-line of family, community, and world events

**Category 4:** To demonstrate the continuity of the patient's life

**Category 5:** To express feelings and emotions

**Category 6:** To explicitly demonstrate the presence, commitment, and support of clinicians and family

# Multivariable analysis of the occurrence of post-traumatic stress disorders (PTSD) in patients

| Variables                 | IES-R score      | p-value | IES-R > 22       | p-value |
|---------------------------|------------------|---------|------------------|---------|
|                           | RR (95% CI)      |         | OR (95% CI)      |         |
| <b>Intervention group</b> | 0.94 (0.78-1.13) | 0.52    | 0.92 (0.54-1.54) | 0.75    |
| <b>Age, y</b>             |                  | 0.02    |                  |         |
| <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                |         |                  |         |
| <b>Gender</b>             |                  |         |                  |         |
| Female gender             | 1.21 (1-1.47)    | 0.06    | 2.29 (1.33-3.91) | 0.002   |
| <b>ICU event</b>          |                  |         |                  |         |
| Unexpected cardiac arrest | 1.65 (1.06-2.57) | 0.03    |                  |         |
| <b>Memories</b>           |                  |         |                  |         |
| Sensations                | 1.39 (1.09-1.79) | 0.009   |                  |         |
| Delusional                | 1.4 (1.12-1.74)  | 0.003   | 3.54 (1.92-6.50) | <.001   |

Variables in the patient multivariable analysis: presence of a diary (forced variable), age, SAPS II score, gender, duration of benzodiazepine, and of fentanyl exposition, weaning failure and re-intubation, delirium, sensations and delusional memories on the basis of a p-value threshold of 0.20. 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 estimated rate ratio (RR) with its 95% confidence interval and corresponds to the effect of each factor on the IES-R score.