

Impact of an ICU diary on the well-being of patients and families in French ICUs: the ICU-Diary study of the Outcomerea research group.

Comité scientifique

Maité Garrouste-Orgeas

Jean-François Timsit

Stéphane Ruckly

Cécile Flahault



Projet
soutenu par

Fondation
de
France

1. Dr Sandrine Valade, Service de réanimation médicale, Groupe FAMIREA, Hôpital Universitaire Saint Louis, Paris
2. Dr Marina Thirion, Service de réanimation polyvalente, Hôpital Argenteuil
3. Dr François Santoli, Service de réanimation polyvalente, Hôpital Aulnay-sous-bois
4. Dr Xavier de Forceville, Service de réanimation polyvalente, Hôpital de Meaux, Meaux
5. Dr Rebecca Halidfar, Service de réanimation médicale, Hôpital universitaire Albert Michallon, Grenoble
6. Dr Isabelle Vinatier, Service de réanimation polyvalente, La Roche-sur-Yon.
7. Dr Virginie Maxime, Service de réanimation, Hôpital universitaire Raymond Poincaré, Garches
8. Pr Jean Paul Mira, Service de réanimation médicale, Hôpital universitaire Cochin, Paris
9. Dr Naike Bige, Service de réanimation médicale, Hôpital universitaire Saint Antoine, Paris
10. Pr Laurent Argaud, Service de réanimation médicale, Groupe hospitalier universitaire Edouard Herriot, Lyon
11. Dr Amélie Bazire, Service de réanimation médicale, Hôpital universitaire la cavale blanche, Brest
12. Dr Jean-Pierre Rigaud, Service de réanimation polyvalente, Hôpital Dieppe
13. Dr Nathalie Thieulot-Rolin, Service de réanimation polyvalente, Hôpital Melun
14. Dr Paul Henri Jost, Service de réanimation chirurgicale, Hôpital universitaire Henri Mondor, Créteil
15. Dr Emmanuelle Mercier, Service de réanimation polyvalente, Hôpital universitaire Tours
16. Dr Hubert Grand, Service de réanimation polyvalente, Hôpital de libourne
17. Dr Nora Amdjar-Badidi, Service de réanimation polyvalente, Hôpital de Pontoise
18. Dr Alain Gaffinel, Service de réanimation polyvalente, Institut Gustave Roussy, Villejuif
19. Dr Nicolas Meunier-Beillard, Service de réanimation médicale, Hôpital universitaire Dijon Bourgogne, Dijon
20. Dr Eric Boulet, service de réanimation polyvalente, Hôpital Pontoise
21. Dr Julio Badie, service de réanimation polyvalente, Hôpital Belfort
22. Dr Yannick Monseau, Service de réanimation polyvalente, Hôpital Périgueux
23. Dr Antoine Rouget, Service de réanimation polyvalente, Hôpital universitaire Rangueil, Toulouse
24. Pr Lila Bouadma, Service de réanimation médicale, Hôpital universitaire Bichat, Paris
25. Dr Olivier Lesieur, Service de réanimation polyvalente, Hôpital de la Rochelle
26. Dr Lilia Soufir, Service de réanimation et de médecine intensive, Hôpital Saint Joseph, Paris
27. Pr Lautrette, Service de réanimation médicale, Clermont Ferrand
28. Dr Floccard, Service de réanimation médicale, Lyon
29. Dr Simon, Service de réanimation polyvalente, Troyes
30. Pr Tamion, Service de réanimation médicale, Rouen
31. Pr Jourdain, Service réanimation médicale, Lille
32. Dr Hamzaoui, Service réanimation médicale, Clamart
33. Dr Cédric Bretonnière, Service de réanimation médicale, Hôpital universitaire, Nantes
34. Erika Parmentier-Decrucq, Service de reanimation médicale, Hôpital universitaire, Lille
35. Dr Eric Kipnis, Service de reanimation chirurgicale, Hopital universitaire, Lille

STUDY PROTOCOL

Open Access



The ICU-Diary study: prospective, multicenter comparative study of the impact of an ICU diary on the wellbeing of patients and families in French ICUs

Maité Garrouste-Orgeas^{1,2,3*}, Cécile Flahault⁴, Léonor Fasse⁵, Stéphane Ruckly^{1,2}, Nora Amdjar-Badidi⁶, Laurent Argaud⁷, Julio Badie⁸, Amélie Bazire⁹, Naïke Bige¹⁰, Eric Boulet¹¹, Lila Bouadma^{1,12}, Cédric Bretonnière^{13,14}, Bernard Floccard¹⁵, Alain Gaffinel¹⁶, Xavier de Forceville¹⁷, Hubert Grand¹⁸, Rebecca Halidfar¹⁹, Olfa Hamzaoui²⁰, Mercé Jourdain^{21,22}, Paul-Henri Jost²³, Eric Kipnis²⁴, Audrey Large²⁵, Alexandre Lautrette^{26,27}, Olivier Lesieur^{28,29}, Virginie Maxime³⁰, Emmanuelle Mercier³¹, Jean Paul Mira³², Yannick Monseau³³, Erika Parmentier-Decrucq^{2,2}, Jean-Philippe Rigaud³⁴, Antoine Rouget³⁵, François Santoli³⁶, Georges Simon³⁷, Fabienne Tamion^{38,39}, Nathalie Thieulot-Rolin⁴⁰, Marina Thirion⁴¹, Sandrine Valade⁴², Isabelle Vinatier⁴³, Christel Vioulac⁴, Sebastien Bailly¹ and Jean-François Timsit^{1,2,12}

Rehabilitation Interventions for Postintensive Care Syndrome: A Systematic Review



2014

POSITIF

Juliane Mehlhorn, MD¹; Antje Freytag, PhD¹; Konrad Schmidt, MD¹; Frank M. Brunkhorst, MD^{2,3}; Juergen Graf, MD⁴; Ute Troitzsch⁵; Peter Schlattmann, PhD⁶; Michel Wensing, PhD⁷; Jochen Gensichen, MD, MPH, MSc¹

The use of diaries in psychological recovery from intensive care



Critical Care 2013, **17**:253

NEGATIF

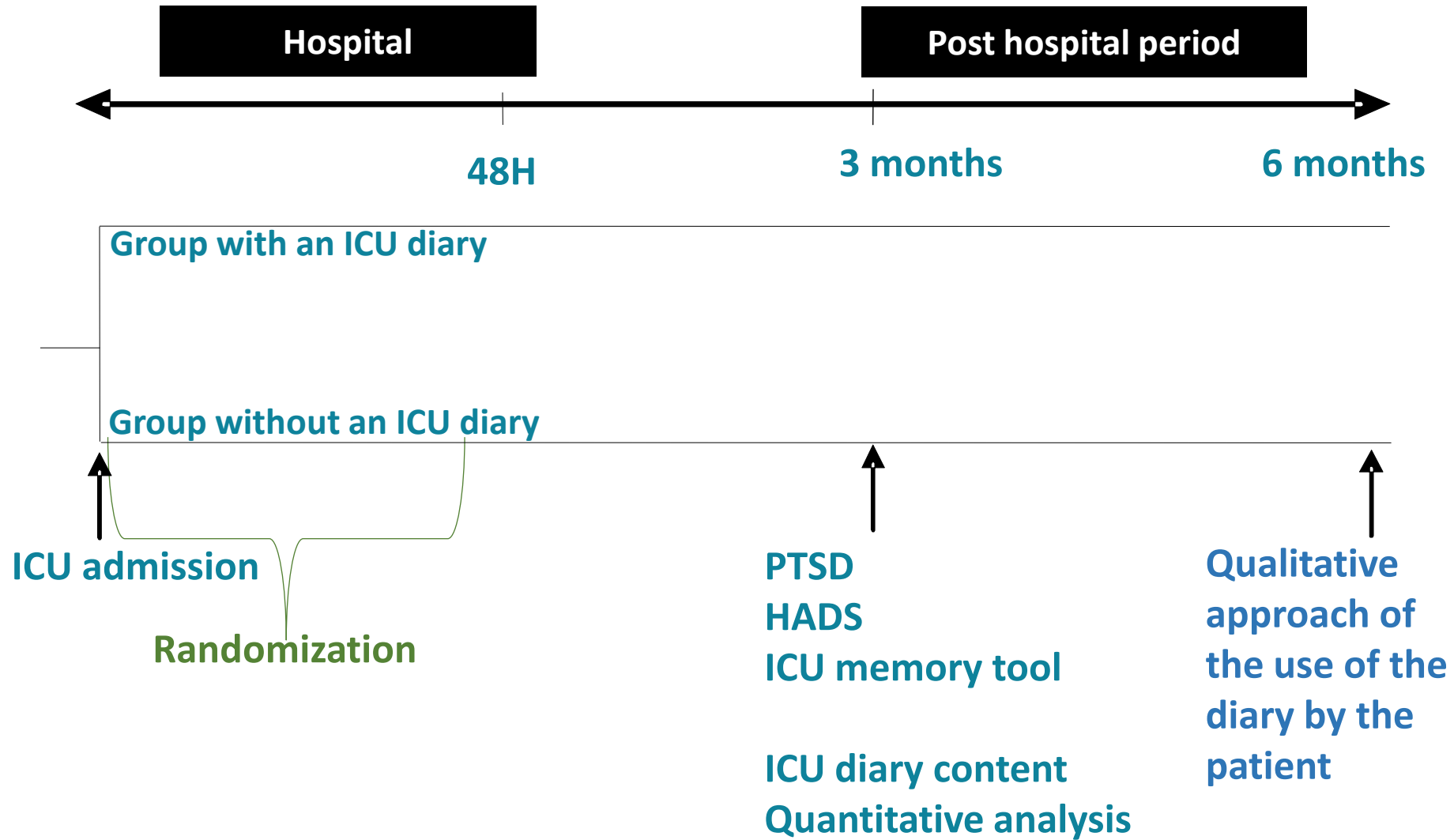
Leanne M Aitken^{1,2*}, Janice Rattray³, Alastair Hull⁴, Justin A Kenardy^{5,6}, Robyne Le Brocq⁵ and Amanda J Ullman¹

The effect of intensive care unit diaries on psychological outcomes and quality of life of survivors of critical illness and their relatives: A systematic review and meta-analysis
Philippa A McIlroy et al

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Design



Primary Outcome

PTSD of the patient 3 months after ICU discharge

Measure of the primary outcome

Percentage of patients with IES-R > 22

Score IES-R

Secondary outcomes

PTSD of the family member 3 months after ICU discharge
HADS of the patients 3 months after ICU discharge
HADS of the family member 3 months after ICU discharge
Memories of the ICU stay

Measures of the secondary outcomes

Percentage of families with an IES-R > 22
HADS score > 8
Use of the memory tool questionnaire

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

Non inclusion 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
- -Patient deprived of liberty
- -Deaf and mute patients

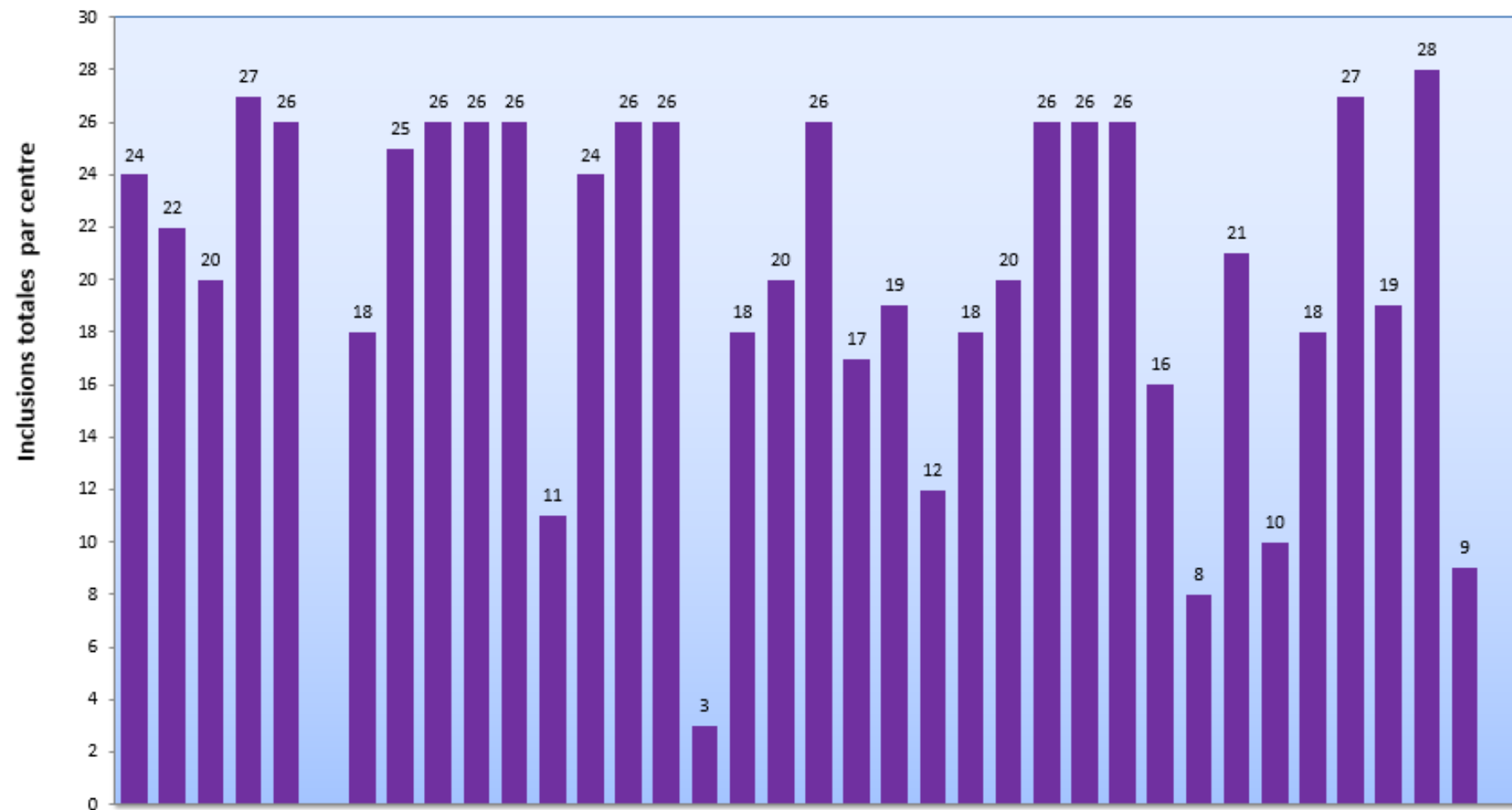
Statistical analysis

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).

The quantitative data will describe the patient's characteristics and the results of the psychological impact using the IES-R and HADS scales in the two arms. The impact of ICU diaries on PTSD will be assessed using a Mantel-Haenszel chi-square test. A Kruskal-Wallis test will be used to compare quantitative secondary endpoint.

Justification of sample size.

Post-traumatic stress related syndrome was reported in 15% [35], 20.7% [50], 51% [19], 64% [22] of patients and in 29.8% [50], 42% [51], 49% [52] and 67% [22] of family's 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 months, considering a mortality rate of 40% and a cumulative rate of 50% of re-hospitalization or impossibility of interviewing the patient (refusal, sequelae 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).



Characteristics of the 35 ICUs

Variables	Data
Hospital	
University hospital, n (%)	21 (60)
ICU	
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	8 (22.8)
Nurse-to-patient ratio, median (IQR)	2.5 (2.5-3)
Nursing-assistant-to-patient ratio, median (IQR)	4 (4-4)
12-hour shifts for nurses, n (%)	27 (77.1)
12-hours shifts for nursing-assistants, 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)

*Les résultats de cette étude sont en cours
d'écriture pour une soumission des résultats
quantitatifs patients et familles*

Merci de votre compréhension