Author’s response to reviews

Title: The ICU-Diary study: Prospective multicenter comparative study of the impact of an ICU diary on the well-being of patients and families in French ICUs

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**Author’s response to reviews:**

NCT02519725 indicates the following
The corrections are in red in the manuscript.

Comment 1. Primary Outcome Measures:

Post traumatic stress disorder symptoms in patients [ Time Frame: 3 months after ICU discharge as measured by the Impact Evaluation Scale-Revised questionnaire ]

Manuscript states

“We will report the score of the posttraumatic stress-related symptoms and the percentage of patients with high PTSD, defined by an IES-R score ≥22, as previously used in ICU studies”

The registration suggests that the proportion of patients with severe PTSD symptoms has been added. Please clarify.

Answer 1. The statistical analysis notified that patient’s PTSD rate will be 40% in the control group and 26% in the intervention group. For this we will use a cut-off of 22 for the PTSD.

Comment 2. Secondary Outcome Measures:

Post traumatic stress disorder symptoms in families [ Time Frame: 3 months after ICU discharge as measured by the Impact Evaluation Scale-Revised questionnaire ]

Manuscript states

The posttraumatic stress-related syndrome in families three months after ICU discharge, using the IES-R scale

Will a proportion of families suffering PTSD be described, as with primary outcome?
Answer 2. We will use the same cut-off of 22. These precisions appeared in CT.

Comment 3. Anxiety and depression related symptoms in patients [Time Frame: 3 months after ICU discharge as measured by the Hospital Anxiety and Depression Scale] Anxiety and depression related symptoms in families [Time Frame: 3 months after ICU discharge as measured by the Hospital Anxiety and Depression Scale]

Aligns with manuscript

“The anxiety and depression symptoms in patients and families 3 months after ICU discharge. These symptoms are assessed using the validated French version of the self-administered Hospital Anxiety and Depression Scale (HADS)”

Answer 3. We modified as you suggested.

Comment 4. Recollection of the memories of the ICU stay by the patient [Time Frame: 3 months after ICU discharge as measured by the memory tool questionnaire] Aligns with manuscript “The recollection of memories of the ICU stay by the patient 3 months after ICU discharge, as measured by the ICU memory tool.”

Answer 4. We changed to memory tool questionnaire through the manuscript.

Comment 5. Other Outcome Measures:

Use of the diary by the patient [Time Frame: 6 months after ICU discharge] Not described in manuscript.

Answer 5. We added this part of the study. At 6-months the patients in the intervention arm will have a phone interview by the psychologist. We added in the manuscript:

Qualitative analysis of patient interviews.
These interviews will be conducted in the intervention arm and will describe how the patient uses his/her diary. CV will conduct the patient interview through direct calls. Each interview will be audio-recorded, transcripted verbatim and qualitatively analyzed to capture the subjective use of the diary by the patient. This qualitative analysis will be done par CF, LF. A large sample of interviews will be subjected to the general inductive approach [49] while other will be subjected to an interpretative phenomenological analysis [50] in order to understand in depth the meaning-making processes of the patients facing intensive care.

Comment 6. Qualitative research using phenomenology interpretative analysis Not described in the outcomes section, deferred until P17 of the PDF under “Diary Content Analysis.”

Answer 6. See above.

Comment 7. Please add the qualitative analysis of diary content to outcomes.

Answer 7. The qualitative analysis of the diary will use the grid of Table 1 where the different themes are listed.

Comment 8. ClinicalTrials.gov indicates “Estimated Enrollment: 520”

Manuscript indicates “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 … we will include 700 patients and their family member in the 35 centers.”

Please clarify.

Answer 8. We obtained an amendment to increase the number of centers and eligible patients in February 2016. I have actualized this point on CT. I add this amendment in the submission.
Authorship

Trials endorses the ICMJE criteria for authorship and appropriate authorship at https://trialsjournal.biomedcentral.com/submission-guidelines/preparing-your-manuscript/study-protocol The text description provided suggests that some authors may not meet all four ICMJE criteria. Please evaluate authorship contributions and ensure ICMJE criteria are met for each of the 41 listed authors. Those not meeting all 4 criteria can be listed in Acknowledgements.

We added data in the manuscript explaining that the authors followed the recommendations for authorships in the section

SPIRIT Compliance

Done