Author's response to reviews

Title: Health related quality of life in cancer patients at the end of life: Translation, validation and longitudinal analysis of specific tools

Authors:

Anne-Lise POIRIER (anne-lise.poirier@ico.unicancer.fr)
Fabrice KWIAKOWSKI (Fabrice.KWIATKOWSKI@cjp.fr)
Jean-Marie COMMER (jean-marie.commer@ico.unicancer.fr)
Bénédicte D’AILLIERES (benedicte.daillieres@ico.unicancer.fr)
Virginie BERGER (virginie.berger@ico.unicancer.fr)
Mariette MERCIER (mariette.berger@unic-fcomte.fr)
Franck BONNETAIN (Fbonnetain@cgfl.fr)

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Author's response to reviews:

To Editors-in-Chief of trials journal:
Doug Altman, Curt Furberg, Jeremy Grimshaw and Peter Rothwell
Subject: online submission of the following revised manuscript “Health related quality of life in cancer patients at the end of life: Translation, validation and longitudinal analysis of specific tools” (Ref 6605979846301417)

Please find enclosed our revised manuscript entitled: “Health related quality of life in cancer patients at the end of life: Translation, validation and longitudinal analysis of specific tools.” which we are pleased to submit to “Trials” journal for publication.

We extend our sincere thanks for accepting our paper pending minor revisions. We agree with these remarks and we have modified the manuscript accordingly. You will find every modification in the text highlighted in yellow. Answers to every point underlined by the Reviewers are also attached in a point by point response. We believe that we have met your requirements and that we have improved this paper.

All authors of this paper have read and approved the final version submitted. All authors of this paper have no conflict of interest to disclose. Thank you for considering our paper for publication in “trials” journal.

Yours sincerely,
Dr Anne Lise Poirier For and on behalf of all authors
Centre d’Evaluation Clinique en Oncologie,
Centre Paul Papin
2, rue Moll 49933 Angers cedex 9
Response to the reviewer’s report

We sincerely thank you for reviewing our paper and criticizing it. We agree with your remarks and have modified the article accordingly. You will find every modification highlighted in yellow in the article, and answers of every point highlighted by reviewers are described below. We hope that we have met your requirements to improve this paper.

Editorial Requests:

1) Please include the Trial registration number in the abstract. If your research article reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number.

We have more detailed this aspect in the study design section and we have added the trial registration number.

The Clinical trial was registered to the Safety Agency for Health Products (AFSSAPS ie Health authority in France). It was registered as a biomedical research while this study does not assess health products. The authorization was in agreement with the Article L. 1123-8 Code of Public Health and was obtained in February 2010. The registration number is 2010-A00196-33.

As suggested we have also added the number registration in the text (Page 6, line 1)

2) Please include a section explaining your trial status. This should follow the ?Discussion? section. The status of the trial at the time of manuscript submission. The journal considers study protocol articles for proposed or ongoing trials provided they have not completed patient recruitment at the time of submission.

We have had a section “trial status” after discussion.

“Between the 15th December 2010 and the 5th April 2011 30 patients have been included in 5 centers to check the understanding of the questions as well as their acceptability. Qualitative analyses of these pre-test data confirmed that questionnaires and translations were acceptable and that the study is feasible. Little adjustment were done related to understanding of the translation : rewording of some items.

At this time the prospective study ie “longitudinal prospective study to cross-culturally adapt the English questionnaires QUAL-E and MVQOLI (Missoula Vitas Quality Of Life Index) and to validate their psychometric properties in the end-of-life setting” is ongoing needing to include 372 patients: 9 centres were open and active and 12 patients has been included since the 8th November 2011”

We have added also a "list abbreviations" to clarify the manuscript.

Reviewer 1:

&

EA 4184 Faculty of medicine, Burgundy University, Dijon France
a) Pagination would be useful.
As suggested we have had pagination.

b) I did not see any reference to registration of the clinical trial. The trial does not assess drugs or devices, but rather the approach to assessment of quality of life in patients with terminal cancer.
Nevertheless, it is not clear that the journal has exceptions for its requirement of registration.
We have more detailed this aspect in the study design section and we have added the trial registration number.
The Clinical trial was registered to the Safety Agency for Health Products (AFSSAPS ie Health authority in France). It was registered as a biomedical research while this study does not assess health products. The authorization was in agreement with the Article L. 1123-8 Code of Public Health and was obtained in February 2010. The registration number is 2010-A00196-33.
As suggested we have also added the number registration in the text (Page 6, line 1)

c) The abstract should mention that there is a randomized clinical trial component in addition to a cohort study component.
Similarly, the study design section (bottom of the fifth page) should also mention the clinical trial.
As suggested we have added the reviewer's propositions.
In the abstract, in the Method section, we have added: "A randomized clinical trial component in addition to a cohort study is implemented in order to test psychometric hypotheses: order effect and improvement of sensibility to change."
In the text, in Study design section (bottom of the fifth page), we have added also the same sentence "A randomized clinical trial component in addition to a cohort study is implemented in order to test psychometric hypotheses: order effect and improvement of sensibility to change..

d) Table 1, particularly the top headings, is confusing. Perhaps it is the way my copy printed out, but I found it difficult to understand. Some of the abbreviations were not spelled out.
As suggested we have clarified the table 1 with columns, and abbreviations were spelled out (D1: First day, the day where the first QoL questionnaires will be completed; D3: 3 days after first day).
e) A minor item: on line 3 of the abstract, the word "entourage" sounds strange (at least to American English) when used in this context. I assume what is meant is "close family and friends."
As suggested we have modified the word "entourage" by patients' family and close friends I the abstract.