Author's response to reviews

Title: Unique characteristics of Korean cancer patients: the perception of clinical trials

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Author's response to reviews: see over
Dear Editor,

We really thank for the thoughtful review on our manuscript. The comments have been so valuable for our paper. We revised our manuscript according to reviewer’s suggestions. Followings are our reply to reviewer’s questions in detail:

**Reviewer: Valerie Jenkins**

**Reviewer’s report:**
Whilst the subject is of great interest, and it is welcome to read the views on clinical trials from Non-Western Nationalities, the manuscript is rather repetitive and should be edited to make it more succinct.

**Major compulsory revisions**

**Abstract**
1. The methods section needs elaboration. For example, is the clinical trial hypothetical?, a VAS scale was used (this is not mentioned until the conclusion).
**Reply**: We added comments about VAS score in abstract.

2. What does well trained research nurse mean?
**Reply**: It means oncology certified nurse who is working in outpatient clinic.

3. The word higher is repeated too many times in the results section.
**Reply**: I rewrote the results section according to your comments.

4. In the conclusion the authors state “our data would help researchers conduct clinical trials successfully in Asia” – How?
**Reply**: As mentioned in discussion section, Korean patients showed unique characteristics about clinical trials. First, even they were more aware of a randomized trial than the West, they didn’t know actual randomization process or assignment of treatment arm in randomized trials. Second, higher level of awareness did not result in more willingness to participate in clinical trials. For first thing, detailed explanation about the process of clinical trials and randomization is needed and for second one, not only just increasing the awareness of clinical trials but also changing the way patients think about clinical trials is essential.

**Introduction**
5. The introduction needs to be rewritten to contain more facts – for example- how many clinical trials are conducted in Korea – what proportion of patients are recruited to trials – how does this compare with the 5% that the authors note in the USA? How does the doctor – patient relationships differ in Asia compared with Western World?
**Reply**: Unfortunately, there is not proper data answering your questions. At SMC, 10-20% of GI/hepatobiliary cancer patients are enrolled in clinical trials. Traditionally in Asia, the family assumes the major role of decision-maker on behalf of the patient.

**Materials and methods**
6. There is some repetition in this section. Break it down into e.g., participants/recruitment/questionnaire details. The questions from the questionnaire can be as an
appendix rather than in the text with a VAS scale, but the questionnaire can be described.
Reply: We put the questionnaire in supplementary material.

7. Was it all self-completed by the patient? How many questions in total – 21 or 21 plus the others? Was a VAS scale used for them all or only the ones shown. It is unclear.
Reply: Yes, it was completed by patient him- or herself. Questions are 21 in total including 4 questions which used VAS score.

Results
8. Again this is so repetitive – see the start of patient cohort – “From July 1st 2011 etc.”
   The word most is repeated throughout. The results section needs to be made more succinct., we already know you used a VAS scale so there is no need to keep saying that.
Reply: We revised it following your advice.

9. Were there missing data?
Reply: No, there isn’t. We looked at the number of patients in table, and found that we made a mistake. In table 1, patients with first line chemotherapy were 257, not 254. There was no missing data.

Discussion
10. Some repetition is found here from the introduction.
   On page 17 you say that “…while a higher degree of education, being married, and high economic status were associated with a higher degree of awareness of clinical trials, these variables were not associated with the actual participation in clinical trials.”
Reply: As we totally agreed with you, that sentence above were deleted in discussion section.

11. The word “actual participation is misleading” because the patients were not being recruited to an actual trial.
Reply: Thank you for your comments. We change “actual participation” to “willingness to participate”.

Conclusion
12. Can the authors suggest how understanding cancer patients’ perception etc would facilitate conducting clinical trials in Asia?
Reply: It is similar question with N.4

Minor compulsory revisions
13. The title has the phrase “unique characteristics of Korean cancer patients” but I think this is misleading as there was not anything “unique” in their characteristics compared with similar publications from other nationalities.
Reply: As mentioned in discussion section, we think that Korean patients showed unique characteristics about clinical trials. First, even they were more aware of a randomized trial than the West, they didn’t know actual randomization process or assignment of treatment arm in randomized trials. Second, higher level of awareness did not result in more willingness to participate in clinical trials.

14. Scattered throughout the manuscript are translation errors e.g. “As the matter of fact……”, this should be “As a matter of fact…” (top page 6), and “In the scale of 10”, this should be “On a Scale of 0 to 10” (Page 12, page 13). There are other similar errors.
Reply: We revised our manuscripts generally.

Reviewer: Andrew Vickers
Reviewer’s report:
This is an interesting study but is often poorly reported.
Major comments
a) Reflect on the participation rate for the conclusions of your study. Surely the 67% who responded to the questionnaire are much more likely to join a clinical trial than those who refused even to fill in a questionnaire? How might estimates change if you took into account those who refused to take part?
Reply: I think that you pointed out important thing. As you said, we further included sentences about this bias into discussion section.

Minor comments
a) Use appropriate levels of precision. No need to use decimal places in percentages or more than 1 decimal place in VAS results. use only one significant figure in p values (e.g. 0.8 not 0.823)
Reply: According to your opinion, we changed our data.

b) Figure 1 includes impossible values (e.g. -5)
Reply: Figure 1 shows the distribution of ‘willingness to participate in clinical trials’ and bar graph designates how many patients answer that VAS score.

c) don’t report means and medians
d) report standard deviations with means
Reply: I’m afraid I can’t report now. If you think it is essential for publication, we need more time for analyzing data at biostatistics core.

e) put the questionnaire in an appendix rather than in the body of the paper.
Reply: As mentioned earlier (#6 of major comments), we put the questionnaire in supplementary material.