Author's response to reviews

Title: Recruitment challenges in clinical research including cancer patients and their caregivers A randomized controlled trial study and lessons learned

Authors:

Karin Sygna (karin.sygna@rr-research.no)
Safora Johansen (Safora.johansen@hioa.no)
Cornelia Ruland (cornelia.ruland@rr-research.no)

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Author's response to reviews: see over
Re Ms. No. 1656551947161942 Recruitment challenges in clinical research. A case study and lessons learned

Oslo, August 2015

Dear editors in chief; Doug Altman, Curt Furberg and Jeremy Grimshaw, Trials journal

We thank the editors for the constructive and thoughtful criticism, we have considered all the comments, and have changed the manuscript according to these suggestions.

Please find a revised version of our manuscript entitled “Manuscript Recruitment challenges in clinical research. A case study and lessons learned” enclosed. These changes are explained in the manuscript file “Manuscript 2-changes with tracks”, while the revised manuscript (without “track changes”) is the file “Manuscript 2-changes with no tracks”. All the changes are marked with yellow in the manuscript, changes with tracks.

We hope that we have addressed all comments satisfactorily and made the manuscript acceptable for publishing.

Thank you again for the review!

Sincerely, on behalf of the authors,

Safora Johansen
Corresponding author

LIST OF CHANGES:

"? In response to reviewer 1, the authors have added the text 'However, this paper describes only recruitment experiences and data related to 370 of the 560 patients and caregiver participants (180 pairs) recruited in February 2013 until July 2014, as the detailed documentation of the remained respondents (160) were not available.?' The authors should add a sentence saying why the data were not available.

Reply: This sentence is now added to the manuscript:
The recruitment team was not aware of the recruitment challenges when they started recruitment and therefore a detailed documentation of the respondents was not assessed from the beginning of the recruitment.
In response to reviewer 1 the authors present the eligibility criteria, which include had access to the internet and had both a bank ID. It wasn't clear to me why participants need a bank ID so a sentence explaining why would be useful. The word both suggests a criterion is missing.

Reply: The following is now added to the manuscript: The recruiter used a checklist to assess the eligibility of the candidates. The eligibility criteria were: the cancer patient and their caregiver was ≥ 18 years old, had a caregiver willing to take part in the study, had access to the internet and had each a bank ID. The recruitment took place in order to test the effect of using a web-based support tool on participants' health and quality of life. For a secure access to this internet-based support tool and preventing the intruder's access, each participant had to have a separate bank ID.

In response to reviewer 1 the authors write 1562 cancer patient candidates for participation in research. For each of these cancer patients there was also caregivers. I still don't think the sentence is clear. The authors should write something like 1562 cancer patient candidates for participation in research. For each of these patients, a carer was also invited to take part or similar.

Reply: This sentence is now added to the manuscript: For each of these cancer patients, a caregiver was also invited to take part in the study.

In response to reviewer 2 the authors mention 'Except for the online and flyer strategies all strategies required considerable researcher time.' I think this line ought to go into the article, it's useful information. It could perhaps go in the Discussion when discussing the cost of the newspaper advertising.

Reply: The following is added to the discussion: Although some opt-in recruitment strategies employed in the present study was cost-effective, it is worth to mention that all the recruitment strategies required considerable researcher time.

In response to reviewer 2 saying that the leaflets were in Norwegian, I think they should just be made available as they are in Norwegian. Scandinavians will be able to read them, as will non-Scandinavians who happen to understand Norwegian and Google Translate will do a good job of getting the gist. Importantly, even without understanding the text, the layout and presentation can be useful.
Reply: All the leaflets are now available, please see the attachment “Employed recruitment leaflets in Norwegian”.

In response to reviewer 2 the authors discuss the term “user-adapted”. I agree with the reviewer that the term is confusing and I don’t think the modified manuscript has improved things because the term remains. As the reviewer says, it suggested that the cancer patients can in some way adapt the recruitment process, which isn’t the case. I would suggest completely dropping the term “user-adapted” unless the authors can explain in very clear language in the manuscript what it means and why the term is justified.”

Reply: The term user-adapted is now removed from the entire manuscript and replaced with the term “routine care letters” as suggested by the reviewer.

Editorial requests

1. Please include the email addresses of all authors on the title page.

Reply: E-mail addresses er now added.

2. Please clarify in your ethics statement in the Methods section that the ethical committee approved the study conduct (as well as the consent procedure).

Reply: The following is added to the methods:

**Ethics**

All participants provided written informed consent, and the study was approved by the Ethical committee of the South-Eastern Norway Health authority of Norway.

3. Please include a list of abbreviations used and their meanings, after the Conclusions section.

Reply: We did have only one abbreviation “full time position (FTP)” founding it unnecessary in abbreviation’s form and therefore removed. We can not find any other abbreviation in the manuscript. We believe then that it will not be necessary to add a abbreviation list.