Author's response to reviews

Title: Who is the research subject in cluster randomized trials in health research?

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Version: 3 Date: 27 June 2011

Author's response to reviews: see over
Dear Dr. Goldsmith,

Thank you very much for sending us further suggestions from two reviewers to improve our manuscript. We describe the changes made to the specific suggestions below.

In addition to the suggested changes we have taken this opportunity to thoroughly edit the article with a mind to improving consistency in terminology, argument, and presentation across the series of articles.

We hope you find the changes made satisfactory.

Yours sincerely,

Charles Weijer.

Reviewer's report #1
Title: Who is the research subject in cluster randomized trials in health research?
Version: 2 Date: 23 April 2011
Reviewer: Charlie Goldsmith

Reviewer's report:
In general, the suggestions made by the 3 reviewers have been well handled.

- Thank you.

Attached is a series of other issues to be considered.
1. P(age) 7, p(aragraph) 3, l 4 and P 8, p 1, l 1. Suggest deleting [in order] in front of [to].

- Done.

2. P 11, p 1, l 3. In the spirit of gender neutral language, suggest replacing [her] by [the] just like p 11, p 3, l 8. Also P 13, p 2, l 4 in the quote, suggest rewriting as [# to meet# the individual#s #needs, #] so that it is clear that you are changing the quote to comply with the neutral concept. Also, P 19, p 3, l 1 of quote, suggest rewriting as [# proceeds in# the physician#s #interaction with a patient to bring what# the physician #considers #]. Also P 19, p 4, l 1, suggest replacing [her] by [the] and on l 2 replacing both [her] and [she] by [the [physician]. Also P 20 p 1, l 2, suggest replacing [her] by [the physician#s]. Also P 38, Item 2, l 2, suggest replacing [his/her] by [the individual#s].

- Done.

Level of interest: An article of outstanding merit and interest in its field
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
I declare I have no competing interests

Reviewer's report #3
Title: Who is the research subject in cluster randomized trials in health research?
Version: 2 Date: 27 April 2011
Reviewer: Elina Hemminki

Reviewer's report:
I would like the authors still to take into account my comment Detail 1. I did not suggest to abolish the distinction between experimental intervention and data collection intervention. I suggested NOT to use the word "intervention" for data collection, as it is misleading.

- We thank the reviewer for the comment and have added a clarification to our definition of the term on page 13: "Interventions (using the term in its broadest sense) refer to the procedures under investigation in both the experimental and control arms of the study, as well as non-therapeutic data collection procedures." The reviewer correctly understands that the term intervention may refer to an "action taken to improve a medical disorder" (in the sense of a study intervention) and procedures for data collection are not interventions in this sense of the term. The term intervention, however, has a broader meaning, viz., "the action or process of intervening", where to intervene is to "come between so as to prevent or alter something". The text now makes clear that we are referring to this broader sense of the term when we discuss interventions on subjects for the purpose of data collection. To further minimize the risk of confusion we refer to "data collection procedures" where possible.

Our usage of 'intervention' in the definition of human research subject is consistent with the use of the term 'intervention' in research regulations. For instance, the Common Rule understands interventions as including "procedures by which data are gathered (for example, by venipuncture)...". Also, the CIOMS International Ethical Guidelines uses the term intervention broadly and refers to "Risks of interventions that do not hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual must be justified in relation to the expected benefits to society (generalizable knowledge)."

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
'I declare that I have no competing interests'