Author’s response to reviews

Title: Comparing the feasibility, acceptability, clinical- and cost-effectiveness of mental health e-screening to paper-based screening on the detection of depression, anxiety, and psychosocial risk in pregnant women: A study protocol of a randomized, parallel-group, superiority trial

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Author’s response to reviews: see over
Nov. 25, 2013
Dr. D. Altman
Editor-in-Chief
Trials
BioMed Central
236 Gray’s Inn Road
London WC1X 8HB
United Kingdom

Re: Submission of manuscript, *Comparing the feasibility, acceptability, clinical- and cost-effectiveness of mental health e-screening to paper-based screening on the detection of depression, anxiety, and psychosocial risk in pregnant women: A study protocol of a randomized, parallel-group, superiority trial* (Please note change in title to conform to SPIRIT guidelines)

Dear Dr. Altman:

Please find enclosed our revised manuscript, “*Comparing the feasibility, acceptability, clinical- and cost-effectiveness of mental health e-screening to paper-based screening on the detection of depression, anxiety, and psychosocial risk in pregnant women: A study protocol of a randomized, parallel-group, superiority trial*”, by Kingston et al. Thank-you very much for the opportunity to revise and resubmit this Protocol. We appreciate the feedback from Dr. Merry and the editorial staff. We have detailed our amendments in the table below.

With sincere appreciation,

Dr. Dawn Kingston, Ph.D, RN (Corresponding author)
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<th>Referee and editorial comments</th>
<th>Manuscript amendments</th>
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<td>1) Please ensure the title conforms to journal style for study protocol articles. The title should follow the format ?__________: study protocol for a randomized controlled trial.?</td>
<td>The title has been amended to: <em>Comparing the feasibility, acceptability, clinical- and cost-effectiveness of mental health e-screening to paper-based screening on the detection of depression, anxiety, and psychosocial risk in pregnant women: A study protocol of a randomized, parallel-group, superiority trial</em></td>
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<td>Please include a figure title and legend section after the reference list. The figures should not be included in the main body of the manuscript.</td>
<td>A figure title and legend section was added after the reference list. This was removed from the figure, and the revised Figure 1 attached.</td>
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| **Minor discretionary**
As I understand it, the design you have undertaken to ensure allocation concealment and blinding appears to rely entirely on your participants following the process correctly, i.e. they will received the information about the allocation, and will then fill in the questionnaires on the tablet or on paper, and will return these to the study team who will be blind to the participants’ allocation. There does not seem to be any check to ensure that they have followed instructions correctly. I can envisage some participants deciding not to follow instructions for example if they would rather fill in the questionnaire on the tablet than on paper, or simply getting it wrong. It would seem to be relatively easy to run a computerised check to ensure the participants are in the correct group, or to run a manual check (perhaps by the research coordinator) on a subset to check the error rate. While I expect any violations would be small in number, it would strengthen the study to be able to address this definitively. | Thank you for this comment. We have added the following statements to page 12 (Procedures):

> Two processes have been designed to ensure that the correct versions of the ALPHA and EPDS are completed (e.g., paper versus electronic) and to avert the possibility that participants might self-select a preferred version: 1) the electronic versions of the ALPHA and EPDS are not available to women in the control group through a programmed ‘skip’ procedure; and 2) the research coordinator will conduct a manual check on a subset of 30 control group participants at three different times in the course of the study to ensure that paper-based versions of the ALPHA and EPDS are completed.

In addition, we added the following statements in 3.6 Procedures (p11-12)

**Maternity clinics** “An automatic ‘skip’ procedure ensures that the electronic versions of the ALPHA and EPDS are bypassed for women in the control group”....” All questions require responses, and thus women cannot proceed past questions with missing answers until completed.”

**Hospital-based antenatal unit:** “An automatic ‘skip’ procedure ensures that the electronic versions of the ALPHA and EPDS are bypassed for women in the control group.” |