Author's response to reviews

Title: A centralised public information resource for randomised trials: a scoping study to explore desirability and feasibility

Authors:

Anne L Langston (a.langston@abdn.ac.uk)
Marion K Campbell (m.k.campbell@abdn.ac.uk)
Vikki A Entwistle (v.a.entwistle@abdn.ac.uk)
Zoe Skea (z.skea@abdn.ac.uk)

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Author's response to reviews: see over
Response to reviewers

Reviewer 1

Major Compulsory Revisions
None requested

Minor Essential Revisions
1. Table 1 is missing.
The reference to Table 1 was mistakenly left in the manuscript. The details that we had originally anticipated providing in Table 1 (about the participants of the study) are now detailed at the bottom of Page 6.

2. Figure 1 is a bit confusing
Figure 1 has been re-designed to make it more readable and more consistent with the text.

Discretionary Revisions
More information on what potential participants asked for with regard to contact details.

A section has been added outlining the responses, starting on page 8.

Reviewer 2

Major Compulsory Revisions
Table 1 is missing.

The reference to Table 1 was mistakenly left in the manuscript. The details that we had originally anticipated providing in Table 1 (about the participants of the study) are now detailed at the bottom of Page 6.

Minor Essential Revisions

1. Reason for accessing consumers via the NARPD
See Page 5. Potential trial participants were identified by a variety of means for this study. Often this was via condition-specific networks, and in particular the National Association for the Relief of Paget’s Disease (NARPD). The NARPD was chosen as an avenue for identifying potential trial participants because two of the authors (ALL and MKC) were involved in the PRISM trial (investigating the treatment of Paget’s disease) which was about to start. This trial was advocated for, and partially funded by the NARPD. Some minor amendments have been made on Page 5 to explain this.

The reviewer also asks if this apparent exclusivity introduced bias. This point has been addressed by the addition of a paragraph on Page 13.

2. Summary of contributions.
The number of interviewees has been corrected from 24 to 25.

**Discretionary Revisions**

1. *Are the trials referred to commercial or non-commercial?*
   We have not made a distinction between commercial or non-commercial trials. The registers referred to may include both. The people interviewed for this study have a combination of commercial and non-commercial trial experience.

2. *Introduction – may want to mention the commitment to openness of drug companies*
   This has now been mentioned in the last paragraph of the discussion.

3. *Summary of contributions – change terminology from ‘representatives’ to just ‘consumers’.*
   No changes have been made in response to this comment as we felt that ‘representatives from patient interest/support groups’ was a more appropriate description. These were often people who worked closely with patients suffering a particular condition but did not necessarily suffer that condition themselves. Therefore they were representatives of (a) people with that condition, and (2) members of their group/association.

4. *First paragraph of discussion – better in Introduction*
   This point is well taken, and the paragraph in question has now been incorporated into the introduction.

5. *Page 12. Discussion inclined towards the negative aspects of a trials database.*
   No changes have been made in response to this comment. It was not our intention to convey the impression that a trials database and centralised information resource were undesirable or unfeasible. However, we did feel that there were many important issues (not addressed by this study) that required debate, research and careful consideration before such a resource should be established. We also appreciate that there is a current drive towards Patient Choice in the NHS, but the practical issues mentioned in the discussion still exist despite this.

6. *Figure 1 is confusing.*
   Figure 1 has been re-designed to make it more readable and more consistent with the text.
Reviewer 3

Major Compulsory Revisions
1. Suggested change of Title
   We are reluctant to change the title as suggested because we are not talking about a resource intended only for participants.

2. Suggested change to the Abstract, methods section
   Refusers are now mentioned in this section

3. Suggested change to Introduction, page 4
   The word ‘new’ has been deleted.

Minor Essential Revisions
1. Suggested change to Abstract, results section (line 3)
   The suggested change has been made

2. Suggested change to Abstract, conclusions section
   The suggested change has been made

3. Suggested change to Introduction
   The suggested change has been made

4. Re-phrasing required in Introduction - Line 8
   A minor change has been made to this sentence to emphasise the point that some participants do not have sufficient information or understanding to make a decision of whether to participate when approached about trials.

5. Re-phrasing required in Introduction - Line 9
   We have reworked this sentence to address the reviewers concerns.

6. Suggested change Introduction, last paragraph
   This paragraph has been substantially rewritten in light of comments from two referees, and the suggested change has been incorporated into this.

7. Re-phrasing required in Methods, page 5
   We have re-worded the sentence to make it clear that we were referring to people with experience in different roles in relation to clinical trials.

8. Re-phrasing required in Methods, Page 6
   As suggested by the reviewer we have added an a example of our topic guide in Appendix 1.

9. Was saturation reached?
   We have added a paragraph to explain that while we may not have identified all possible information requirements, we are confident that we have identified the main ones.