Author's response to reviews

Title: Clear obstacles and hidden challenges: Understanding recruitment from the perspective of recruiters in randomised controlled trials

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Author's response to reviews: see over
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Dear Editors

Re: MS: 4019929071065992 – Clear obstacles and hidden challenges...

Thank you for your email on 25th October, and for the helpful reports from the reviewers. Please find attached a manuscript with tracked changes highlighting all the changes, and a point-by-point response to the editorial requests and concerns raised by the reviewers below.

Editorial requests

1. Contributions and acknowledgements moved as requested.

2. The names of the Ethics Committees have been included in a paragraph at the end of the paper and referred to in the Methods (p.6).

3. A competing interests section has been added before the reference list.

4. The revised manuscript conforms to the journal style.

Response to reviewers’ comments

The reviewers’ comments have been reproduced in italics, with a response below (R: ):

Reviewer 1

Discretionary Revisions

1. In methods section:

a) tabulation of numbers and process might improve clarity (rather than 'most' and 'mostly').

R: Table 1 contains specific information about numbers and types of interviews; the text has been clarified (p.6).

b) Clarify what is meant by ethnographic and iterative approach to analysis. And c) You say "based on techniques of constant comparison AND grounded theory" - would this be more accurately described as the constant comparative element OF grounded theory?

R: These comments have been addressed (p.6).

2. In the results section:

a) it may be helpful to breakdown your findings into subheadings, but not essential.

R: The results section already has several sub-headings. These have not been changed.

b) Characteristics of RCTs and participants might be more clearly presented in tabular form

R: The characteristics of the RCTs and participants are included in Table 1.

3. I presume that the manuscript was submitted for review before the launch of the "Ok to Ask" campaign. Nevertheless, I think that it would be pertinent to make reference to this initiative within the paper, probably within the discussion section as the findings presented here may impact upon the extent of its success.

R: This was the case. A sentence has been added in the discussion (p.9).
Major compulsory revision

4.1. The identification of respondents in terms of their roles in the RCT. I do not think that the identification of respondents is clear enough or specific enough. It is not enough to know whether the respondent was a doctor or nurse/other. Whilst I believe that this manuscript gives a clear and informative account of the impact of 'recruiter' behaviours and beliefs on the RCT recruitment process and on the outcomes of that process, I think that this requires clarification. In the results section: 'recruiters' were employed purely in a research capacity, in a hybrid 'research clinician' role, or whether they were employed in clinical roles with an expectation that they would also undertake some research activities. It would also be useful to know whether different combinations and ratios of these roles were in existence - eg which studies had a 'purpose made' research team and which relied solely on ad hoc assistance from clinical staff? I understand that there are a number of different roles involved in RCT recruitment and subsequent management, and that these roles can vary considerably across different sites or within different specialities and indeed for different studies. In the interests of clarity and in the interpretation of these important findings, I would request that the authors provide clear definitions of the roles of different personnel involvement in the recruitment process(es), and identify them as such when giving quotes. By this, I mean that it would be useful to know whether the 'recruiters' were employed purely in a research capacity, in a hybrid 'research clinician' role, or whether they were employed in clinical roles with an expectation that they would also undertake some research activities. It would also be useful to know whether different combinations and ratios of these roles were in existence - eg which studies had a 'purpose made' research team and which relied solely on ad hoc assistance from clinical staff?

R: the formal employment status and roles of the recruiters have now been explained in the text (p.7). As these are clear in each of the RCTs, and there is a clear contrast between two groups of RCTs, this has not been recorded by each quotation as suggested above. However, the point made by the reviewer is a very important one, and sentences have been added to the findings (p.15, 16) and consideration of the potential implications of these issues has also been added to the discussion (pp.19-20).

Reviewer 2

Discretionary revisions.

1. Methods paragraph 1 the authors make reference to 'some simple quantification'. I saw no evidence of this in the manuscript and wonder whether the sentence refers to the reports produced for the individual RCTs rather than the synthesis presented here?

R: The reviewer is correct. This has been removed (p.5).

2. Methods paragraph 2. The readership of the current journal may not be entirely familiar with qualitative methods and processes and with this in mind I find this paragraph a little vague particularly with regard to how the thematic framework was developed initially, whether the same framework was applied to all trials and what "cross-checking of the coding frame within the team" entailed. Similarly I would prefer to see more details of the methods employed to conduct the synthesis; all to provide a little more transparency for the reader.

R: This has now been done in combination with the comments of reviewer 1, p.6.

3. I feel the discussion section could be tightened and hence reduced in length considerable without loss to the arguments.

R: We have reconsidered the content and length of the discussion and do not think it is possible to reduce or tighten it significantly. Many of the findings are novel and have implications for RCT recruitment, and as this is such an important issue for so many RCTs, we do not wish to do this. The reviewer did not suggest specific areas for reduction, and it was identified as discretionary.

Minor issues not for publication: Discussion paragraph 3 line 2 - is the word 'been' missing between "as they have" and "in other studies" - I'm not sure.

R: we have replaced 'have' with 'were' to improve clarity (p.18).
Reviewer 3

Minor Essential Revisions

1. p. 4 line 4 “that” is repeated; 2. p. 8 fourth quote (T7-D4) uses an abbreviation MDT which I don’t think is spelled out previously; 3. p. 9 line 13 “practise” should be “practice”; 4. p. 21 line 19 “and preferences” should be deleted

Discretionary Revisions

1. p. 4 states “Recruitment is an interactional activity and can only occur after at least two meetings...”. I take the point here, however, there are a variety of ways of recruiting which don’t always involve the participant meeting anyone in person. I would suggest that “can only” be replaced by “typically only” to reflect alternate ways of recruiting.

R: This has been done.

2. Also on p. 4 I think perhaps more emphasis could be put on the fact that studies of recruitment to trials rarely examine the process that occurs and whether what recruiters actually do impacts on the success of the recruitment effort. This study together with other studies undertaken by the investigators are some of the few that have looked at this. Yet if one observes the recruitment process or talks to recruiters individual differences in recruiters themselves clearly does have an impact.

R: This helpful suggestion has been included in a new short sentence (p. 4).

3. The study counts one to one interviews and group interviews as equivalent. Yet we know that data generated in groups is typically different to that provided by individuals. It would be useful if this was discussed in terms of any impact it may have had on the data collected.

R: This has now been added briefly to the limitations (p. 21).

4. p. 22 notes that recruitment “is not an activity that all doctors and nurses can or should undertake, and those with very strong views about treatments or stereotyped views should clearly not undertake recruitment.” This statement begs the question – how are we to identify such healthcare workers if as the study suggests those most likely to hold such views may not have the insight to recognise the likely impact on recruitment. It would be useful (if the word limit allows) to perhaps discuss what might be done, or point to this as an area for future research. Similarly, if “individual practitioners will need to acknowledge the anxiety and emotion they experience” it would be helpful to begin to think how this can be enabled.

R: These issues are very interesting but it is really beyond the scope (and length) of this paper to speculate on how these things might be achieved. A sentence suggesting that RCT leaders need to consider these issues has been added to the conclusion (p. 23).

5. Overall, the findings would be strengthened by the use of a theoretical framework or frameworks to support the interpretation. It is clear that issues of clinical identity and the formation/presentation of the self are at work here and it would be useful if these issues were unpacked to provide greater insight about what has been identified (for example why clinicians appeared to lack insight about the impact of their views on the success of the recruitment effort).

R: Again, this is a very interesting suggestion, but the research here has been presented to expose the issues found from the synthesis of findings in these six RCTs. There are many potential theoretical frameworks that could support the findings, but these will need to emerge from future papers based on studies currently underway in many more RCTs, focusing on specific issues.