Author's response to reviews

Title: Influences on recruitment to randomised controlled trials in mental health settings in England: a national cross-sectional survey of clinical studies officers working for the Mental Health Research Network

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

**RE: Manuscript 2111595925108459: Influences on recruitment to randomised controlled trials in mental health settings in England: a national cross-sectional survey of researchers working for the Mental Health Research Network**

Thank you for considering our manuscript reporting a study into factors influencing recruitment to RCTs and for the opportunity to submit a revised version. We are grateful to the reviewers for their considered and helpful comments. We note their generally positive tone but also value the opportunity to improve the paper by addressing the concerns they raise. We respond to each of the points raised below.

We look forward to your decision in due course.

Best wishes,

Dr Sue Patterson
(on behalf of authorship team)

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**Reviewer: B.L.**

1. **The text needs a thorough edit, as there are numerous grammatical and syntactical errors, with frequent us of sub-clauses in sentences. The article lacked clarity as a result.**

   OUR RESPONSE: We have carefully edited the full manuscript to eliminate grammatical and syntactical errors. In doing so we have simplified the language to improve clarity. We have edited each of the sentences which the reviewer highlights.

2. **The introduction and discussion also lacked focus. The summary overstates the findings from the data and the conclusions are not justified. The survey instead reflects the views of CSOs which is interesting and valid, but does not provide any other data to be able to say whether these views have any association with actual recruitment. So we do not know whether the CSOs reporting difficulty with culture and attitude amongst healthcare workers also recruited fewer patients as a result.**
OUR RESPONSE: We trust that our editing has enhanced the focus in introduction and discussion. In relation to overstating findings, we acknowledge this as important critique and have reconsidered and revised the text. We have modified our discussion of study limitations and our summary conclusion to make the constraints on the findings explicit. In particular we have noted the findings represent only one perspective (albeit a multi-vocal one) and that experience and views will have been shaped by the actions of CSOs and their interactions with gatekeeping clinicians. It may well be that the experiences of CSOs reflect their own frustrations and capacity limitations and have included a statement to this effect reflect the responsibility that comes with resources. It behoves researchers, CSOs and the MHRN to work actively to support clinician and service engagement and minimise the burden of research activity.

3. I found it interesting that the discussion focussed on the difficulties experienced with the gatekeepers, and what the clinical services should do to change, rather than the effectiveness of CSOs or the MHRN itself. After all, the NIHR was established by taking R and D money away from NHS clinical services and setting up a ring-fenced separate entity. So the results of the survey could be seen as a necessary reflection of this separation, but the net effect has still been a huge increase in research activity in mental health services as a result.

OUR RESPONSE: We appreciate this observation and the background information which we now acknowledge in the manuscript.

4. I thought the positive suggestions from CSOs as to what was helpful in recruitment interesting, and in particular the comments about being more integrated into the clinical teams. Is it possible for the authors to stratify the responses depending on the level of integration of the CSOs to see whether this has a positive effect on their perception of the culture of the clinicians. So for instance some CSOs had offices with in clinical teams, and I would expect that their responses to the questions of engagement would be different.

OUR RESPONSE: The CSOs indeed made useful suggestions which we were pleased to report. Unfortunately we are not able to ‘stratify’ responses. We did not ask CSOs to specify their work location and because so few CSOs spontaneously reported being embedded in teams this would potentially compromise anonymity.

Reviewer: Sujit D Rathod.

Major compulsory revisions

1. The low response rate is concerning, especially given the topic of this paper. Is it not possible for the authors to compare their sample’s characteristics against any data available on the overall MHRN population? For example, with regard to age, sex, years of practice and specialty?

OUR RESPONSE: We share the reviewer’s concern about the modest response rate. Unfortunately we are not able to compare characteristics of the respondents to those of CSOs as a group as no such data is held collectively by the MHRN. Whilst it is possible, as noted in our discussion, that another or a larger sample may have refined or challenged current findings, we cannot speculate about the similarities/differences between those who responded and those who did not.
2. Page 8: The results described in the sentence "Participants reported qualifications..." is not part of Table 2. Also, Table 2 does not include all qualifications listed by participants.

OUR RESPONSE: We have restructured the first paragraph of the results section for clarity and amended the reference to table 2. We have now added a section on ‘Professional qualifications’ to Table 2.

3. While the authors have carefully described the issues identified with recruitment into general RCTs, they provide little justification for there being unique issues with recruitment into mental health RCTs. Is there any empiric evidence for there being a particular problem with recruitment into mental health RCTs, and especially do in the UK? What is the evidence to say that "the conduct of trials needed to reduce the massive burden of disease is particularly challenging"? Is there reason to believe the MHRN is not reaching its potential?

OUR RESPONSE: We have restructured the introduction to more clearly articulate the concerns which have been identified in the mental health context. We note that in addition to the generic challenges faced across services and trials, recruitment in mental health context is complicated by the ‘vulnerability’ attributed to the population due to the nature of mental illness. References are provided.

In relation to the reviewer’s final point about the MHRN, we did not set out to evaluate the work and outcome of the MHRN and we therefore cannot offer any evidence-based comment. Whilst this is an interesting and important question, our aim was to better understand trial recruitment with a focus on gaining access to potential participants.

4. In the Discussion, as in the Background, the authors must take particular care to highlight any findings that appear to be unique to mental health RCTs. That no other reviews of research methodology are cited in the Discussion to put these findings into context is a concern.

OUR RESPONSE: This is a very important observation. We have amended the introduction to more clearly articulate challenges identified in mental health contexts - and the potential for characteristics of the population to influence recruitment in particular ways. To date, to our knowledge, given the case study approaches taken to investigation of recruitment no papers have described factors which are specific to mental health settings. In our discussion we note that the findings of this study are consistent with others in the mental health context and note the importance of undertaking comparative studies in the future. The penultimate paragraph in the discussion (copied below) has been extensively revised to reflect address these points:

“While we set out to explore recruitment to trials in mental health, we note that the recommendations grounded in our data could be seen as generic in that they could apply across health care domains. Determining which factors, if any, influencing recruitment are peculiar to ‘mental health’ would require a comparative approach which our study did not have, but which we would encourage other investigators to adopt. However, the elusiveness of clinical gains amongst many mental health service users, the fragility of these gains given the high rates of relapse and the reality that when gains are achieved they often require treatment over the long term, may be one key influence. It is possible that this generates a conservative and cautious approach to gatekeeping amongst mental health workers who when invited to judge the potential positive and negative consequences of participation may see the scales tipped to often towards the negative. Further research is
needed to explicate the complex relationships between researchers and clinicians to support development of the necessary alliances. It seems particularly important that clinicians’ voices are heard.”
OUR RESPONSE: We have now added the following sentence at the beginning of the Results section:

“Summary data are shown in Table 2 along with means (M) and standard deviations (SD).”

We have also added denominators throughout the Results section, as requested.

10. In the Results, pair the qualitative findings with specific figures from the quantitative findings. It is preferable to report the percentage of respondents who affirmed a given item #, rather than just identifying the item #. There are several points in the Results where the authors assert a point but do not support it with their data.

OUR RESPONSE: We have now clarified and enhanced the qualitative findings by pairing each of our assertions with the quantitative data.

11. "...CSOs argued strongly that robust, 'real' feasibility studies were crucial..." Feasibility studies of what?

OUR RESPONSE: Thank you for drawing our attention to use of a term which may be misunderstood. We have removed the word ‘real’ and clarified now that feasibility studies should realistically assess recruitment potential, with attention to service stability and culture as well as stakeholder interest and capacity.

12. In the References, Item #13 lacks a publisher or city.

OUR RESPONSE: We have amended this in the revised manuscript.

Discretionary revisions

13. The authors can consider reserving the term "participant" for those individuals who are enrolled in the randomized controlled trials. It is slightly confusing when "participant" refers to the CSOs in the present cross-sectional study.

OUR RESPONSE: We thank the reviewer for pointing this out. We agree and have changed ‘participant(s)’ to ‘respondent(s)’ when referring to CSOs who returned the survey questionnaire.

14. Replace "URL" with "website", or define the acronym.

OUR RESPONSE: We have now amended this to ‘a link to the online survey.’

15. The sentence starting "Researchers have located barriers..." is confusing.

OUR RESPONSE: We have amended this sentence and it now begins ‘Barriers to access to potential participants have been located within....’

Consider revising.

16. Page 10: "THE consensus amongst participants..."

OUR RESPONSE: We have made this amendment, thank you.
17. Page 6: "This was informed by a literature review..."

OUR RESPONSE: We have made this suggested revision, thank you.