Author's response to reviews

Title: Challenges to be Overcome using Population-Based Sampling Methods to Recruit Veterans for a Study of Post-Traumatic Stress Disorder and Traumatic Brain Injury

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Author's response to reviews: see over
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Dear Editor,

Thank you for your letter regarding the review of our manuscript “Challenges to be overcome using population-based sampling methods to recruit veterans for a study of Post-Traumatic Stress Disorder and Traumatic Brain Injury” for consideration by the journal BMC Medical Research Methodology (MS ID : 1509507343109907).

We have addressed reviewer comments in a revised version of the manuscript and we describe these changes below point-by-point. The comments were very helpful and we believe these revisions have greatly enhanced the manuscript. We hope that you will find the manuscript suitable for publication in the journal BMC Medical Research Methodology.

Thank you for your consideration,

On behalf of the co-authors

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Reviewer 1.

Major Compulsory Revisions

1. The reviewer disagrees with the conclusion that TBI patients once contacted were less likely to complete screening (Results/Discussion). The reviewer points out that if those with TBI and PTSD were treated as having TBI then there was no significant difference in screening based on TBI status. We agree with the
reviewer, and we have now added this analysis (Results, p.14-15). We point out in the text that the TBI results are found in the TBI only group. We have also modified the Discussion to comment on this finding and have removed reference to the TBI group effect in the conclusions (p.19). The reason for these observations are not apparent but we speculate in the Discussion that they are due to the small sample size of the “pure” TBI group (n=4) rather than their putative diagnosis of TBI which we originally speculated was influencing their willingness to participate.

2. The reviewer correctly states that recruitment challenges extended well beyond problems in contacting participants. This is shown by the observation that 84% of those contacted failed to enroll. We have now modified the Discussion (p.18 - 19) to state that our ability to contact potential participants was only one of a number of factors associated with recruitment. We have now added text stating that 84% of those contacted failed to enroll (Discussion, p.18). We have also added details of participant compensation (Methods, p.11) and have added a discussion and a reference detailing factors that may have influenced enrollment, especially compensation (Discussion, p.18).

3. The reviewer noted a lack of discussion of incentives or compensation. We refer the reviewer to our response to item #2.

4. We thank the reviewer for bringing the Millennium Cohort Study to our attention in relation. We have cited the two papers mentioned by the reviewer as excellent examples of how to contact and follow-up with veterans, and have added a third citation that refers to the origins of the study (Ryan, M. A., Smith, T. C., Smith, B., Amoroso, P., Boyko, E. J., Gray, G. C., . . . Hooper, T. I. (2007). Millennium Cohort: enrollment begins a 21-year contribution to understanding the impact of military service. J Clin Epidemiol, 60(2), 181-191.)

Secondary/Minor revisions

1. The reviewer noted that Table 5 shows that 23 participants enrolled whereas all other text states that 24 enrolled. The reason for the discrepancy is that one participant withdrew consent after taking part in the study (as noted in the legend to Fig. 1), and therefore this individual was removed from Table 5. We have re-entered this individual into Table 5, and there is now consistency across the manuscript.

2. The reviewer asked how any members could be too old, as shown in Table 4, since age would be known before inviting participants into the study. We agree that this should have been the case. However, screeners were given lists of eligible patients to screen but due to the often-lengthy process of contacting the veterans, some had passed the cutoff age.

3. The reviewer asked why “sub-threshold PTSD” would make participants ineligible as identified in Table 4. One of the aims was to determine the prevalence of TBI and PTSD, to identify sensitive and specific measures for them, and to develop prediction models. Thus, we were recruiting individuals that reached full (currently utilized) diagnostic criteria, not individuals with sub-threshold symptoms. We have clarified this point in the “screening procedure” (p.11).

Reviewer 2.

Discretionary Revisions
1. The reviewer noted that on page 18, it is unclear whether the text refers to travel by study staff or travel by participants. We have now modified the text to state more explicitly that resources for travel support and hotel accommodations are for the potential participants (now p.20).

Minor Essential Revisions

1. The reviewer noted that the New Generation Study (NGS) is described as “ongoing” but raised the question of why the contact information for participants was out of date. The NGS participants have not been re-contacted after they completed the survey, except for the current study. We have deleted the word “ongoing” to make this clear (p.6).
2. The reviewer asked how potential participants could be ineligible because they were not veterans of OEF or OIF, as shown in Table 4, since all participants in the NGS were supposed to be veterans of OEF and OIF. We thank the reviewer for bringing this to our attention. This was a typo error in Table 4. The text in Table 4 now states “Deployed to OEF/OIF for < 30 days”.
3. The reviewer noted that the MIND study was mentioned three times before it was referred to as a pilot study. We have now modified the text to refer to the MIND study as a “pilot study” when it is first introduced on page 6, and have provided more history to the pilot on p.8.
4. The reviewer noted Table 5 shows that 23 participants enrolled whereas all other text states that 24 enrolled. The reason for the discrepancy is that one participant withdrew consent after taking part in the study (as noted in the legend to Fig. 1), and we removed this individual from Table 5. We have now re-entered this individual into Table 5, and there is now consistency across the manuscript.
5. We thank the reviewer for bringing to our attention that the header for Table 2 should say, “one of the 80 individuals contacted but not screened”, and have modified this text in Table 2.
6. The reviewer asked for clarification for the role of the “initial contact only” in the screening procedures (p 11). Some individuals were screened on the same call, while others were willing to be screened but made an appointment for a later date. We were unable to contact some of these individuals again after the initial call, and they were categorized as “initial contact only” in Table 2. We have added text to now p.12 to explain this issue.

Major Compulsory Revisions

1. The reviewer asks what sample size was targeted and whether the objective was met. As we now state in the Introduction (p.8), the sample size of the MIND study was n=800. The MIND pilot study was conceived following changes in funding priorities and had a target sample of n=60. During execution of the pilot study, priorities again changed before this n=60 target was reached. The reasons behind these project changes were largely unrelated to scientific or recruitment issues. For this reason, we felt that comparisons between the cohort recruited and the NGS are not critical and did not describe them in detail. However, we have now provided more context about the origins of the MIND pilot study especially in relation to the larger MIND study (p.8).
2. The reviewer asked whether there were any important differences between the contacted and not contacted groups based on demographic and clinical information from the New Generation Study. We performed an analysis to compare these two groups across demographic variables (age, gender) and putative diagnostic category taken from the New Generation Study. We found no statistically significant differences. We now report this analysis in the Results (p.14).

The reviewer also asked whether the proportion of the New Generation Study whose “best address” indicated they lived within 60 miles of a WRIISC site (n=445) was representative of the New Generation Study as a whole. The MIND pilot sample (n=445) was compared to a sample of deployed veterans from the New Generation Study (n=13,162). This sample was slightly larger than the 11,337 reported in Figure 1 because it included veterans >50 years old who did not meet age criteria for the MIND pilot study. The two samples were not statistically different in age or gender (p’s >.05). However, a chi-squared test revealed a significant difference between the two samples in putative diagnostic groups ($\chi^2 (3) = 47.8$, $p < .001$). Examination of $\chi^2$ residuals showed the MIND pilot sample had fewer individuals with a positive screening result for TBI (11% vs. 16%) or PTSD (9% vs. 16%) relative to the New Generation Sample. Furthermore, the MIND pilot sample had more individuals with a positive screening result for combined TBI and PTSD relative to the New Generation sample (15% vs. 7%). The proportion of individuals with neither TBI nor PTSD were similar across the MIND pilot and New Generation studies (65% vs. 61%, respectively). Although these between-group comparisons are statistically significant, we suggest the two samples are relatively similar overall, and statistical differences are driven by the very large numbers involved (e.g., the largest difference was 15% vs. 7% for combined TBI and PTSD). We have now added these analyses to the Results (p.13-14) and commented on them in the Discussion (p.16).