Author's response to reviews

Title:"A systematic review of training programmes for recruiters to randomised clinical trials"

Authors:

Daisy Townsend (daisy.townsend@bristol.ac.uk)
Nicola Mills (nicola.mills@bristol.ac.uk)
Jelena Savovic (j.savovic@bristol.ac.uk)
Jenny L Donovan (jenny.donovan@bristol.ac.uk)

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Author's response to reviews: see over
Authors’ Comments:

We would like to thank the editorial team for sending our paper out to review and the reviewers for their helpful comments. We have listed our responses to each point raised by the first reviewer and highlighted the changes made to the manuscript. No changes were requested by the second reviewer. We look forward to your response.

Reviewer 1:
Major Compulsory Revisions

• Can a sample search strategy (e.g. for MEDLINE) be presented as supplementary material. It would be of interest to see which search terms were used and how they were combined, particularly as this is a complex intervention.

Response: Thank you for this suggestion. This has now been added to the supplementary material (additional file 1).

• Were foreign language papers included? Were any experts in the field contacted? Were ongoing trials databases searched? Any ongoing trials may be relevant in the context of future research recommendations.

Response: Thank you for raising this. Due to practical reasons, we did not include foreign language papers. In the methods section on page 6, we have now stated that ‘non-English papers were not translated due to lack of resources’. We acknowledge that this is a limitation of the review and in the discussion on page 17, we have added ‘As non-English papers were not included due to lack of resources, there may have been studies in other languages that were missed’.

Whilst we did not contact experts in the field in the identification of study stage, we did contact authors of papers that were identified as relevant for further clarification of their studies (in terms of methodology and findings). On pages 6-7 of the methods section, we have added, ‘Where necessary, corresponding authors were contacted to request further clarification regarding study details.’ We hope that this is now clearer.

Clinical trial databases were not searched for ongoing trials as we were not looking specifically for clinical trials, and types of studies that are subject to this review are rarely registered on trial registers. Even if the host trial they are nested in is registered, the registration record usually do not include any details on nested methodological studies carried out within a trial. We did however search ERIC, which is a good resource for educational programs.

To distinguish between clinical trials and training programmes (where participants were randomised to training versus control groups within a host RCT), we have changed how we use the abbreviation ‘RCT’, which is now only used to refer to host clinical trials or randomised clinical trials in general. We now refer to the randomised studies that were included in the review as ‘randomised studies’, without abbreviation, throughout the text.

• 2.2. Selection of eligible studies. Can the relevant comparators and outcomes be stated.

Response: Thank you for pointing this out. Although eligibility criteria have already been described in the methods section, we have now presented them in a more structured way, explicitly according to PICO criteria, as follows (page 5):

2.1 Criteria for inclusion of studies

Study types: All randomised, non-randomised or qualitative studies were eligible for inclusion. Due to the exploratory nature of the review, no studies were excluded by quality.

Participants: Health professionals and other trial staff involved in patient recruitment into RCTs.
Interventions: Training interventions delivered to trial personnel involved in patient recruitment into randomised clinical trials, with the aim of improving recruitment into trials or generally improving the success of trials, were eligible for inclusion. Any method (i.e. teaching packs, workshops) and mode (i.e. role play, presentation) of training was examined. Studies that evaluated only general communication training for health professionals not linked to RCT recruitment (i.e. the delivery of bad news) were excluded.

Comparison interventions: All types of comparison interventions (e.g. studies where training was compared to no training or a different training package) as well as studies without a comparison group were eligible.

Outcomes: The primary outcome of interest was host RCT recruitment rates. We also assessed the following outcomes when they were available: numbers of patients approached for recruitment to host RCTs, recruiter self-confidence, patient understanding of trial information and perceptions of recruiter communication, and observation of recruiter-patient trial consultations using pre-determined criteria.

- Methods. There is no section on analysis/synthesis.

Response: We appreciate you bringing this to our attention. On page 7, we have now added the following section:

2.4 Data synthesis
We had planned to do meta-analysis of studies that have reported improvement in recruitment rates (our primary outcome) if sufficient number of studies with combinable outcomes were identified although it became evident that studies were too heterogeneous. Consequently, all outcome measures (including recruitment rates, numbers of patients approached for recruitment to host RCTs, recruiter self-confidence, patient understanding of trial information and perceptions of recruiter communication, and observation of recruiter-patient trial consultations) were analysed descriptively.

- Quality assessment:

  o Was the method of randomisation appropriate for the RCTs?

Response: Randomisation was assessed as a separate domain according to criteria set out in Part B of the EPHPP quality assessment tool for quantitative studies. The two reviewers (DT and NM) independently judged each study on whether randomisation was used, and if so, how this was described and whether the method was appropriate. Judgements were compared and any areas of discrepancy were resolved by examination of the papers and discussion amongst the two reviewers and third author (JS) where necessary. Table 2 shows the agreed quality assessment for randomisation.

  o How were the important confounders determined, and what were they?

Response: We considered confounding as a separate domain that contributed to the global quality rating, as part of the EPHPP quality assessment tool for quantitative studies. Both raters (DT and NM) independently assessed whether each study had controlled for confounders in the design (by stratification or matching) or in the analysis, according to criteria set out in the EPHPP guidance notes. Judgements were compared and any areas of discrepancy were resolved by examination of the papers and discussion amongst the two reviewers and third author (JS) where necessary. In the current review, common confounders were whether participants had received previous training (relating to RCTs or communication skills) and seasonal variations in recruitment. We have provided more information about the confounders on page 8.

  o Presumably blinding refers to outcome assessors only, as participants cannot be blinded. This may be worth stating.
Response: We agree that as it should be noted that participants cannot be blinded, and have now stated this in table 2 with a footnote.

- How is confounding assessed for a pre-/post-test design?

Response: All designs (including studies with a pre-/post-test designs) were assessed as per the EPHPP tool’s instruction. Specifically, strong ratings were assigned to those studies which controlled for at least 80% of relevant confounders, moderate ratings were given to those studies which controlled for 60-79% of relevant confounders, and weak ratings were given when less than 60% of confounders were controlled for or the control of confounders were not described. In uncontrolled studies, seasonal variations in recruitment was the key potential confounder that we considered.

- How did one RCT have poorer quality in terms of confounding compared with some of the other study designs?

Response: Thank you for pointing out that the Kimmick RCT [14] had been noted to be poor quality in this domain. In light of your comments, DT, NM and JS revisited this paper to double check all quality assessments according to the EPHPP quality assessment tool. The assessment of confounding was reported incorrectly and so is now rated this as strong (i.e. they controlled for at least 80% of relevant confounders). We therefore appreciate you highlighting this, as it affects the global assessment of the quality of the RCT (the overall quality rating is now a ‘Moderate’).

In light of this, we revisited the quality assessment of all studies in relation to each other leading to minor changes in some study ratings (Table 2 has been subsequently updated). In particular, we have now changed the description of the Jenkins [24] study design. We had originally described it as a randomised controlled design for the primary outcome (patients approached) with the secondary outcome of confidence discussing trials assessed before and after the workshop as a pre-test-post-test evaluation. On further scrutiny and with additional information from the author, we now understand that the recruiters were randomly allocated to either 12 or 6 months of audit before and after the training, while all participants in both groups received identical training. Outcome measures (including patients approached and confidence discussing RCTs) were measured for all participants before and after the training was delivered, making this study a pre-test/post-test design in the context of our review. The manuscript text and relevant tables/figures have been updated where necessary. These subsequent changes do not, however, affect the review’s conclusions.

- Why were the ‘intervention integrity’ and ‘analyses’ criteria of the EPHPP quality assessment tool not used, and how would this affect the global quality rating?

Response: We did not use the ‘intervention integrity’ (Part G) and ‘analyses’ (Part H) criteria of the EPHPP quality assessment tool as the tool dictates that only the first six domains (Parts A-F) contribute towards the global rating. Other systematic reviews in the same field (such as Fletcher B, Gheorghe A, Moore D, Wilson S, Damery S: Improving the recruitment activity of clinicians in randomised controlled trials: a systematic review. BMJ Open 2012, 2:496. doi:10.1136/bmjopen-2011-000496) have also excluded these two criteria and have only reported the six categories.

- Page 6/7. “Key weaknesses related to the potential for selection bias and confounders”. Some more detail/examples would be useful here. Why weren’t participants representative? (E.g. were they self-selecting?) What were the most important confounders?

Response: Thank you for your suggestion, we agree this should have been clearer. On page 8 we have now stated:

‘Selection bias was most frequently related to the fact that participants were self-selecting or were excluded from the intervention if they did not recruit sufficient numbers. Common confounders were whether participants had undergone any previous training (relating to RCTs or communication skills) and seasonal variations in host RCT recruitment rates, particularly in uncontrolled pre-post studies.’
In the discussion on page 17, we have stated:

‘Two studies excluded participants from the training session as they did not recruit sufficient numbers [23, 25], although it could be argued that these individuals may have benefited most from training and support.’

- Overall, a bit more depth is needed for the description of quality assessment. Perhaps an assessment of how well the global tool worked across the different study designs could be added to the discussion. The findings should also be discussed more in the context of quality, e.g. did the studies with strong or moderate quality rating find different results overall to those with a weaker quality rating? How did reporting issues affect the quality rating?

Response: Thank you for your constructive comments. In the article, we have stated how quality was assessed (page 6):

‘Quality assessments were performed using the Effective Public Health Practice Project (EPHPP) quality assessment tool for quantitative studies, which assessed studies by selection bias, design, confounders, blinding, data collection methods and withdrawals and drop outs [18]. The quality of qualitative studies was assessed using the Critical Appraisal Skills Programme (CASP) checklist, which covered rigour, key research methods used, credibility and relevance [19]. Quality assessment of all eligible studies were completed independently by two reviewers (DT and NM). Individual assessments were compared and any areas of discrepancy were resolved by examination of the papers and discussion amongst the two reviewers and with the other co-authors.’

We have also provided Tables 2 and 3 (which provide a breakdown of the agreement for each domain of the quality assessment). Following on from the reviewer’s previous comment, we have also added examples of key weaknesses in regards to selection bias and confounding bias (page 8):

‘Selection bias was most frequently related to the fact that participants were self-selecting or were excluded from the intervention if they did not recruit sufficient numbers. Common confounders were whether participants’ had undergone any previous training (relating to RCTs or communication skills) and seasonal variations in host RCT recruitment rates, particularly in uncontrolled pre-post studies’

In the review, the findings of each study included in the review are reported according to the outcome measure and study design (pages 10-14). In the discussion, page 14 compares the findings of the different study designs. The conclusion (pages 18) calls for the use of robust methods to test the effectiveness of training programmes, so that the training and support needed to improve recruitment rates while maintaining high levels of informed consent can be more reliably determined. To address the reviewer’s concerns, and discuss the findings more in the context of quality, we have rewritten the opening discussion paragraph so that it now states (page 14):

‘Findings suggest that RCT recruiter training programmes are acceptable to recruiters and may increase their self-confidence and communication of key RCT concepts to patients. Studies with less robust study designs also suggested that training has the potential to improve recruitment rates and aspects of patient satisfaction and understanding of RCTs. However, the review found limited high quality evidence of interventions aimed at recruiters and therefore demonstrates the need to develop more robust designs to develop an evidence base on how best to target this group for training in trial recruitment. More comparative studies, especially randomised or clustered randomised trials, are the ideal method to assess the effectiveness of such training programmes.’

- How comparable were studies in terms of comparator arm (where applicable)? For example, standard practice in one hospital/study in terms of training may differ to standard practice in another. Further, standard practice in one hospital may be similar to the intervention in another hospital.
Response: Most included comparative studies compared a training intervention with no intervention. The training programmes included a wide range of health professionals who were involved in recruiting to many different types of RCTs. As a result, it is not possible to ascertain what standard practice is for each RCT within each centre.

• Research recommendations. Which study design would you recommend for further studies? Which were the main biases identified that future studies should aim to minimise?

Response: In the first paragraph of the discussion, on page 14, we have now added: ‘More comparative studies, especially randomised or clustered randomised trials, are the ideal method to assess the effectiveness of such training programmes.’

Minor Essential Revisions

• The labelling is not consistent between Figure 1 (3 non-randomised controlled trials) and table 1 (2 non-randomised controlled trials and 1 prospective case controlled study). What is meant by a “prospective case controlled study”? Case-control studies are normally retrospective so this warrants an explanation.

Response: Thank you for pointing this out. We have now updated Figure 1 so that it is consistent with all data in the tables. The authors themselves had identified the study as a “prospective, case-controlled intervention study”. However it is clear from the methods section of this article that the recruitment teams have been randomly allocated to either attend the training session or receive no training. We have thus corrected this and this study is now labeled as randomised in all tables and figures.

• Table 3. Can ‘study design’ be added as a separate column.

Response: This has now been added, although to avoid repetition we combined Tables 1 and 3 to make one table (now Table 2).

• Can a distinction be made in Figure 1 between “studies” and “papers”

Response: In Figure 1, we made the distinction between ‘papers’ and ‘studies’ since not all papers that were identified and read in full were research studies (as the third box shows, two were commentary - these were obtained to examine the reference lists).
Reviewer 2:
I think this is a good article that highlights a step in the recruitment process that could have a significant impact on recruitment rate yet is difficult to monitor or control. It points out the discrepancy between the governance for written v. verbal communication and explores whether training for recruiters could be a way to improve recruiter performance with benefits for both the study and the patients. This systematic review is an important first step in developing the evidence base. It is clearly written and follows a robust methodology. The results are mainly descriptive due to a lack of studies with similar training programmes or outcomes. The discussion and conclusions are well balanced and give sensible recommendations for future research on recruiter training.

Response: We would like to thank this reviewer for taking the time to review our study, and are very pleased to see that the study was well-received and no changes are required.