

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis.
AUTHORS	Mitchell, Elizabeth; treweek, shaun; Lockhart, Pauline; Pitkethly, Marie; Cook, Jonathan; Kjeldstrøm, Monica; Johansen, Marit; Taskila, Taina; Sullivan, Frank; Wilson, Sue; Jackson, Catherine; Jones, Ritu

VERSION 1 - REVIEW

REVIEWER	Patrina Caldwell Staff Specialist and Senior Lecturer The Children's Hospital at Westmead and The University of Sydney Australia There are no competing interests
REVIEW RETURNED	18-Dec-2012

THE STUDY	The supplemental documents are appropriate
GENERAL COMMENTS	This systematic review update is well conducted using standard methodology. The author mentions 3 previous systematic review on the topic, but did not add his own previous review (ie there are 4 previous review on the topic). The conclusions of this review are the same as the previous review by the author, and so have little additional information to add. Perhaps this should be mentioned in the abstract.

REVIEWER	Fiona Campbell Reseach Fellow School of Health and Related Research University of Sheffield Regent Court 30 Regent Street Sheffield S1 4DA
REVIEW RETURNED	19-Dec-2012

RESULTS & CONCLUSIONS	There is little reference to the earlier systematic reviews and their findings. This review is described as an update, and include additional studies. However, it does not describe how these have changed or not changed the conclusions from earlier work. Therefore it is unclear what additional insights this work brings. The review by Watson '06 describes the importance of culturally appropriate recruitment strategies. This was not discussed in this review. It would be useful to have a clearer idea where this work sits
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	in terms of new knowledge. Otherwise, a well conducted research project and well presented paper.
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REVIEWER	Fay Crawford Senior Health Services Researcher Newcastle upon Tyne NHS Hospitals Foundation Trust UK I have no competing interests
REVIEW RETURNED	20-Dec-2012

GENERAL COMMENTS	<p>Thank you for inviting me to referee this interesting manuscript. The authors have taken some trouble to prepare their excellent Cochrane review in a more accessible format for publication in BMJ Open. The original review will have been subject to extensive peer-review and this has benefitted this second, high-quality manuscript which is well-written and has clear messages. I assume BMJ Open has a dual-publication agreement for Cochrane reviews? I only have a few comments to make about the manuscript.</p> <p>Implications for future research</p> <p>One or two methodological suggestions as to how to evaluate recruitment strategies within trials would be helpful –example(s) of ways to design such a trial.</p> <p>I do wonder if using multivariable regression methods to identify the factors associated with successful recruitment strategies for trials is a better way to answer the question and if the authors agree may wish to incorporate this into the Implications for future research section.</p> <p>Formatting</p> <p>There are some BMJ Open conventions that have been over looked and the authors should consult the advice for authors again http://group.bmj.com/products/journals/instructions-for-authors/formatting/</p> <p>I couldn't find;</p> <ul style="list-style-type: none"> • Up to five keywords or phrases suitable for use in an index (it is recommended to use MeSH terms). • Word count - excluding title page, abstract, references, figures and tables. <p>The referencing doesn't conform to the BMJ Open style;</p> <p>"Use one space only between words up to the year and then no spaces. The journal title should be in italics and abbreviated according to the style of Index Medicus. If the journal is not listed in Index Medicus then it should be written out in full. List the names and initials of all authors if there are 3 or fewer; otherwise list the first 3 and add et al. Except JMG, which lists all authors. The year of the document should be represented in four-digit format. The volume should be bold".</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1:

1) The author mentions 3 previous systematic reviews on the topic, but did not add his own previous review (i.e. there are 4 previous reviews on the topic).

- As reported in the Introduction, this review updates and builds on that of Mapstone et al (2007). It has identified three times as many studies, as well as studies targeting additional areas of recruitment, including strategies aimed at those recruiting to studies, not just those being recruited. The fourth review that the reviewer mentions is simply an earlier iteration of the current review, available through the Cochrane Database of Systematic Reviews. As such, we have not included it in the list of previous reviews.

2) The conclusions of this review are the same as the previous review by the author, and so have little additional information to add. Perhaps this should be mentioned in the abstract.

- For the reasons given above, we have not altered the text of the abstract.

Reviewer 2:

1) There is little reference to the earlier systematic reviews and their findings. This review is described as an update, and includes additional studies. However, it does not describe how these have changed or not changed the conclusions from earlier work. Therefore it is unclear what additional insights this work brings.

- We have included an additional paragraph to the end of the 'Limitations of the review' section of the Discussion to clarify the contribution of this review to the evidence base (page 16). The additional text reads:

"However, this review provides an update to previous reviews in the field, identifying a greater number of relevant studies and presenting new evidence relating to trial design (the potentially negative impact of using a Zelen design), the approach to participants (the benefits of using SMS messages, framing of trial information, financial disclosure), and financial incentives (including a cash incentive with the trial invitation). In addition, it has generated further evidence to support the broad conclusions from earlier work, namely that opt-out procedures, open rather than blinded trials, paid participation, and telephone reminders to non-responders improve recruitment, while various methods of consent and the provision of supplementary information appear to have little effect."

2) The review by Watson '06 describes the importance of culturally appropriate recruitment strategies. This was not discussed in this review. It would be useful to have a clearer idea where this work sits in terms of new knowledge.

- Although using materials that are culturally sensitive seems sensible, the evidence for it improving recruitment is rather thin. We included two of the studies that Watson and Torgerson refer to in this regard (Larkey et al, 2002; Ford et al, 2004). Larkey et al involved few participants and failed to correct for clustering, although trained Hispanic recruiters did recruit more than untrained Hispanic recruiters. For Ford et al, Watson and Torgerson report the same findings as we do: that only one strategy produced a small improvement in recruitment. Both studies had moderate risk of bias. Watson and Torgerson also included interventions aimed at increasing response rates to materials mailed to patients. We excluded interventions of this type as this is covered by another Cochrane systematic review (Edwards et al, Methods to increase response to postal and electronic questionnaires. Cochrane Database Syst Rev 2009; 3: MR000008). One of the two studies falling into this category included by Watson and Torgerson included culturally sensitive materials (Kiernan et al 2000) and they found no benefit from using these.

Given the points detailed above, we do not feel as enthusiastic as Watson and Torgerson about the use of culturally sensitive materials as a recruitment intervention (there are, of course, other good reasons for making materials culturally sensitive). We do not believe that the evidence presented in our review supports highlighting culturally sensitive materials as an area particularly ripe for further evaluation. Perhaps more research would be useful but we think that other interventions, such as financial interventions and SMS-based interventions, are better candidates for this. We would prefer therefore to leave our text unchanged. We do, of course, reference the Watson and Torgerson review and interested readers will be able to compare and contrast the two reviews and come to their own conclusions.

Reviewer 3:

1) Implications for future research. One or two methodological suggestions as to how to evaluate recruitment strategies within trials would be helpful –example(s) of ways to design such a trial.

- This is a good suggestion. We have added the following text to the 'Implications for future research' section of the Discussion (page 16).

"Where uncertainty exists around two or more strategies, an evaluation could actually help trialists to focus their efforts on the most effective strategy (or strategies) while at the same time adding to the methodological literature. If recruitment is carried out in phases, the evaluation could be used in the early phases with later phases employing the most effective strategies identified.⁶³ Since everyone receiving a recruitment intervention 'counts' for the evaluation – the study is simply counting the number of yes and no responses – statistical power is generally not a problem. Graffy and colleagues have discussed nested trials of recruitment interventions in more detail.⁶⁴

2) I do wonder if using multivariable regression methods to identify the factors associated with successful recruitment strategies for trials is a better way to answer the question and if the authors agree may wish to incorporate this into the Implications for future research section.

- The McDonald study that we reference early in our review (Reference 2) did use multivariable regression to look for factors affecting recruitment. We have added a sentence and another reference to the McDonald study, along with the full HTA report from which the Trials paper originates, to the 'Implications for further research' section of the Discussion (page 17). The additional text reads:

"Other authors have used multivariable regression to look for factors that influence recruitment, although there were few insights gained from this.^{2, 67} However, this approach may be worth revisiting as more evaluations of recruitment interventions are published."

3) There are some BMJ Open conventions that have been over looked and the authors should consult the advice for authors again. I couldn't find up to five keywords or phrases.....; Word count.....

- The comment relating to keywords has not been addressed as per the editor's suggestion.
- The word count (excluding title page, abstract, references, figures, tables etc.) has been added to the title page of the manuscript.

The referencing doesn't conform to the BMJ Open style.

- The reference list has been altered to conform to BMJ Open style.

We hope that we have dealt with the suggestions made by the reviewers adequately. Please do not hesitate to contact me if further clarification on any of these points is needed.