Reviewer’s report

**Title:** Reflecting on the methodological challenges of recruiting to a UK-wide multi-centre randomised controlled trial.

**Version:** 2  **Date:** 27 May 2013

**Reviewer:** Bridget Young

**Reviewer’s report:**

This article is a narrative piece reflecting on the challenges encountered in recruiting patients to a particular trial and the lessons learnt from the trial. It does not appear to be presented as a formal empirical article and it does not easily fit with any of the article types (e.g. protocol, research, commentary etc) listed on the Trials website. However, the website also states that Trials encourages publication of articles about specific trials that discuss specific issues of the trial design; aspects of the trial conduct… ; and lessons learned: "What we would do differently knowing what we know now". I have reviewed the article with this publication policy in mind.

**Major compulsory revisions**

1. Please identify the article type.
2. Please provide a structured abstract.
3. There are several references to the lack of previous literature on recruitment to trials. I agree that the scale of the published literature probably does not reflect the scale of the problems in trial recruitment. However, there are now several published systematic reviews on recruitment in addition to the one by Treweek that you cite. So, I’m not sure how accurate it is to imply that this problem is very rarely aired. For example see: i) Rendell JM, Merritt RK, Geddes J. Incentives and disincentives to participation by clinicians in randomised controlled trials. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: MR000021. DOI: 10.1002/14651858.MR000021.pub3; ii) Caldwell PHY, Hamilton S, Tan A, Craig JC (2010) Strategies for Increasing Recruitment to Randomised Controlled Trials: Systematic Review. PLoS Med 7(11): e1000368. doi:10.1371/journal.pmed.1000368; iii) Fletcher et al BMJ Open 2012;2:e000496 doi:10.1136/bmjopen-2011-000496. Please acknowledge this prior work and revise the article to focus on what additional potential insights are offered by the current article.
4. Please provide a section in the discussion reflecting on the limitations of narrative reflective articles. This might acknowledge the value of more systematic approaches to examining and addressing recruitment difficulties, including the use of qualitative research (e.g. see work by J Donovan BMJ 2002; 325 doi: http://dx.doi.org/10.1136/bmj.325.7367.766). The discussion should also acknowledge of the role of patient and public involvement and consultation with recruiters in enhancing recruitment.
Minor essential revisions

5. I tried to find reference 3 reporting the results of the POPPY trial. However, this reference appears to be a published abstract rather than a full paper. Please indicate in the reference list that this is an abstract.

6. Page 2, paragraph 4, sentence 3: please clarify a) whether the recruitment problems were encountered in the pilot or main trial b) what was “the active treatment”.

7. Page 3, paragraph 4, it is not clear what the sentence “Subsequent visits were offered (n=6) when necessary…” refers to. Was it 6 per centre or 6 in total? Did these visits actually take place or were they just offered?

8. Page 6 - the section on “Collaborator and Participant Incentives” includes some interesting and potentially useful reflections about centres and recruiters. However, there is no content in this paragraph on participants so the title should be amended.

9. Page 7, paragraph 5: please revise the second of last sentence, as it is currently unclear.

Discretionary revisions

10. Page 5, paragraph 3: this could helpfully refer to work by Mills, Donovan et al., on the value of exploring patient treatment preferences at the point of recruitment (see J Clin Epidemiol. 2011 October; 64(10): 1127–1136. doi: 10.1016/j.jclinepi.2010.12.017). Given that patients in the POPPY trial knew their treatment allocation, I do not see the relevance of the final sentence in this paragraph.

11. The discussion could refer to what considerations and evidence guided the selection of strategies to enhance recruitment to POPPY. How far were strategies based on pragmatic considerations and how far were they informed by previous experience, consultation with patient and public representatives, consultation with recruiters/centres, etc?

12. In relation to point 3 above, the conclusion could comment on how the evidence base on clinical trial recruitment could a) be improved and b) be made more easily accessible to the trials community.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests