Reviewer's report

**Title:** Inclusion completed! Recruitment barriers and strategies to overcome them in a randomized controlled trial for people with schizophrenia.

**Version:** 1  **Date:** 29 August 2013

**Reviewer:** Verity Leeson

**Reviewer's report:**

- Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

1. The article begins with a thoughtful review of the barriers to recruitment, with specific references to studies in mental health. However, from this point on the article seems to lack a clear identity. It promises to examine recruitment challenges and how these were overcome. It therefore seems unnecessary to have included so much detail on the RCT study itself (e.g. the rating scales used on the study, randomisation technique) and the method section should be substantially trimmed to only reflect the information relevant.

2. In the Background, the authors write that “even though strategies to overcome recruitment barriers have been described [5,9] they have not very often been evaluated [2]”. However, this article does evaluate the strategies it employed as it implies that it will, as no attempt is made to determine the impact of each of the strategies or compare their success other than by personal interpretation on the part of the authors in the discussion. This fact is acknowledged in the conclusion (“The limitations of this study are that the challenges and the strategies are descriptive, based on our experiences and not based on structured data collection. Neither can we directly confirm that the strategies caused the completion of the trial; we can only assume that the strategies had an impact.”). This comes at the end though, after I had spent the entire reading of the article expecting more than was delivered.

3. In “organizational challenges and barriers” (page10) the article states that changes to the AOTs accounted for a considerable change in the number of expected eligible patients. However, it is not clear where this has come from on examination of the table. Aside from the fact that the word “expected” seems to be incorrectly included in this comment, there is a more fundamental issue concerning how this was determined. I can see that fewer eligible participants were identified than expected, although no statistics are presented even for this. How does this show that changes to AOTs were responsible? The authors suggest that the late inception of AOT 2 and AOT3 had an impact but this is not evident in the table as fewer eligible participants were counted in AOT3 but not AOT2 when compared to AOT1. Analyses should be included here if the authors wish to make these points. Nearly a page is dedicated to the various figures for delay to opening, understaffing and actual participant recruitment in the AOTs which is very personal to the study and seems unnecessary to include if these
figures are not used to support the conclusions using analyses. A few percentages in table 1 could replace all of this.

Any number of factors could be responsible for under-recruitment in the study and/or at one site and the authors’ conclusions about what was to blame seems to be based entirely on their own perception. Other factors are listed that “had an impact on the slow recruitment in the project” and, again, in some cases the confident attribution of responsibility seems to be overreaching without any supporting evidence such as clinical staff interviews or analyses to compare sites or identify relationships between factors. For example, a “change of departmental management” is blamed without any further explanation. I am sympathetic to the authors’ conclusions but the lack of presented supporting evidence yet available data make for a confusing presentation. If the authors intend to simply discuss issues that they felt were relevant, this wording of these claims should be substantially toned down to reflect the speculative nature of the statements. The sections on recruiting professionals and eligible participants are more obviously based on the authors’ perception of the difficulties encountered and are easier to read as a result.

- Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

4. The authors report that 103 sealed envelopes were produced with 50 participants in each of the study groups – need to account for the other 3.

In conclusion, this article did not have a clear narrative and needs to be re-written to be the reporting and obviously personal interpretation of the barriers experienced by the trial, and the methods employed in order to achieve successful recruitment. Alternatively, the authors may wish to make more of the data that they have reported and analyse it in order to support their hypotheses about the barriers experienced and success of the strategies employed. At the moment it is not clear which is intended but neither is clearly achieved.

Note: no statistics are presented and so a statistical review is not necessary or possible.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**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