Reviewer’s report

**Title:** Did the trial kill the intervention? Experiences from a randomised controlled trial of a complex intervention.

**Version:** 2  **Date:** 17 August 2010

**Reviewer:** Corrine Voils

**Reviewer’s report:**

This manuscript presents results of a qualitative study involving former trial participants and staff members involved in the conduct of the trial. The data present views on the difficulties associated with delivering a complex intervention. This is a very novel and interesting use of qualitative methodology to learn lessons applicable to the conduct of trials. I applaud the authors for this effort and hope this paper will stimulate similar investigations. The paper would benefit from the following clarifications.

**Major compulsory**

1. It is unclear whether the goal of the qualitative study was to investigate the issues reported herein or whether the issues arose in the midst of asking about other issues. Knowing this will help frame the results.
2. More detail is needed about the trial from which these data stem. What was the goal of the trial? What was the main outcome and hypothesis? This has implications for sampling of participants for this study.
3. Some headings do not match the content of the sections. For example, the “Trial Design” section seems to be more about characteristics of the interventions themselves rather than the design. The end of the section on Operationalization (e.g., inclusion criteria about time since surgery) seems to be more about generalizability and acceptability of the intervention.
4. The section on “practicalities of delivering the HPL programme” is rather brief and should be extended. The authors briefly mention transport and location, but there is not description of relevant issues.
5. Much of the discussion, while well-written, seems irrelevant to the data at hand. The issue of randomization being a confusing process, pointing to the need for a better consent process, does not seem as relevant as the fact that people have preferences. Potential participants may well understand what randomization means but still have a preference and choose not to enroll or put in little effort if randomized to the undesired arm because of their preferences. Similarly, most of the content on the top of p.16 doesn’t seem relevant to the data.
6. The information in the strengths and limitations about the person who conducted the interviews belongs in the methodology. More details are needed as well. Did this person have previous contact with participants, or was s/he just
a coordinator of activities? Was this person actually the interventionist? Did participants understand this person’s role?

Minor compulsory

1. How did participants vary in terms of their level of success in the study? One could imagine that viewpoints would differ between responders and nonresponders.

2. It would be useful to provide more detail on the questions included in the interview guide (Appendix or Table).

3. Were the themes consistent across trial participants and staff members? It would be useful to examine responses in a theme X qual study participant matrix to determine if this was the case.

4. Do the authors know why patients and especially staff members had biases toward the HPL intervention?

5. The summary statement could be extended to offer recommendations or implications stemming from these data.

Discretionary

1. It would be helpful to edit out the nonessential parts of the quotes (um, erm).

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

**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.