Reviewer’s report

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

Version: 2 Date: 30 July 2010

Reviewer: Moira Stewart

Reviewer’s report:

This paper is an adjunct to an earlier paper, reporting quantitative results from a RCT of a rehabilitation programme following stem cell transplantation. The objectives set out in the abstract describe the results given in the paper. However, in the main text, "methods" and "patient interview" (P5) also refer to interviewees' perceptions of the rehabilitation programme, as well as involvement in RCT, which are not included in results and discussion. I suggest clarification, either by including all emergent themes from interviews or explaining why concepts relating to rehabilitation were omitted.

The methods are described on P5. It is not clear whether interviews were individual (implied) or conducted as focus groups, and if the qualitative aspect was part of the original study, or added in light of difficulties in recruitment etc. Did staff, in particular, know that they would be interviewed?

On P8, lines 5, 6-I had difficulty understanding the wording- might be clearer if changed to "..reflecting their prior conviction of the effectiveness of the HPL programme".

The 3 emergent themes are described in detail but were there other themes? The trial design concept describes the problems in relying on staff to recruit patients to a RCT where they are already committed to a particular intervention. This should be highlighted in the summary—should recruitment to similar studies be undertaken in a different way, or after, rather than before, exploring recruiters’ perceptions of appropriateness of RCTs.

The limitations are stated, especially the recruitment rate and numbers in the RCT. The paper, while well written, is limited in its generalisability to evaluation of complex interventions, due to these limitations, the relatively rare patient group and that it was not the main focus of the study.

There are a few grammatical errors eg line7, P17, which are easily corrected.

In summary, despite the very specialised group of patients and also staff involved in the study, the paper does add to the philosophical debate around evaluation of complex interventions. The inclusion of qualitative results on patient perceptions of rehabilitation would have added a further dimension.

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 I have no competing interests.