Reviewer’s report

Title: Can user testing of a clinical trial patient information sheet make it fit-for-purpose? - a randomised controlled trial

Version: 1 Date: 28 March 2011

Reviewer: martin tolich

Reviewer’s report:

The paper addresses a major problem in informed consent by providing a contrast between a standard and modified PIS under experimental conditions. Modification of the revised PIS followed a small sample pilot test of the original document. The authors' modification significantly enhanced the PIS readability. This is an important topic.

(The paper has no page numbers)

The paper’s readability could be significantly enhanced throughout if precise examples of confusions within the PIS were included within the paper.

i.e. Section heading “development phase: results .....ii) "Participants were experiencing some problems with understanding the allocation of treatments and finding information about data storage."

This is a short paper and examples i.e. data storage would assist the reader.

There are three places on this page where examples could be given.

Note: Examples are given later i.e....from “disease going into complete remission” to “getting rid of the leukaemia”;

Providing examples would aid readability.

Plain English: Section 2) Finding and understanding scores.

I have read this brief section a number of times without comprehension. “to find answers to questions” What answers, what questions?

There are two issues in the article’s research design that lessened the impact of the paper. First, there is widespread concern in the literature about whether subjects actually read the PIS. To standardise this study all subjects should have been required to read the PIS under experimental conditions. The authors state that that 41.4% of subjects read the PIS again, before the trial. Were they reading it for the first time? The authors don’t know.

The second research design issue may confound the results. Should there have been three research groups: 1) reading the original PIS, 2) reading the modified or rewritten PIS and 3) reading the rewritten and graphically enhanced PIS. Note: the modified PIS is not only rewritten but it was reformatted. Which is more important? Rewriting or Reformatting? An opportunity was lost here.
Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

‘I declare that I have no competing interests’