Reviewer's report

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

Version: 2 Date: 31 May 2011

Reviewer: martin tolich

Reviewer's report:

I originally wrote:
"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."

This issue has not been addressed in the paper and I would suggest a slight modification to the text.

They wrote on page 15 "All participants read the sheet at home and 48...." THIS SHOULD BE CORRECTED TO "All participants HAD THE OPPORTUNITY TO read the sheet at home and 48...."

Other than this correction I would support the paper's publication.

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'