Author's response to reviews

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

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Author's response to reviews:

University of Leeds
12th May 2011

Dear Editor

Thank you for your email of 26th April 2011. We have amended the paper based on the two reviewers' comments and also those of another senior academic who offered to read the paper.

We have made the following changes:

Reviewer Martin Tolich

• Request for more examples of sheet revisons: examples added to pages 10 and 12;

• Finding and understanding scores paragraph: altered wording in this paragraph (page 14);

• Comment on prior reading of the PIS: added clarification to page 15;

• Comment on research design: added comment to page 16.

Reviewer Karel van der Waarde

• Comment on percentages in the abstract: amended abstract (page 2);

• Comment on readability formulae: we partly agree with the reviewer and have amended the paragraph accordingly (page 5);

• Comment on the explanation of the testing procedure: we have amended paragraph on page 8;

• Request for the whole revised PIS to be available: we would prefer not to
include all of the revised PIS as figures. We have added an additional page – so 2 of the 7 pages are now included. Our preference would be to release the whole PIS to interested readers on request.

• Comment on trial phase outcomes sentence: amended page 12;

• Comment on percentages (or their lack) in the discussion. Our preference would be to not include the exact percentage figures here. Our view is that the discussion should report only a summary of the results, which is consistent with the approach we have taken.

• Readability guideline citation: amended (page 21).

There are a few other minor changes to the paper, all marked with ‘tracking’.

I am sure these changes have improved the paper and hope it now meets the standard required for publication.

Regards

Peter Knapp