Reviewer's report

Title: Improving recruitment to a study of telehealth management for long-term conditions in primary care: two embedded, randomised controlled trials of optimised patient information materials

Version: 1 Date: 20 March 2015

Reviewer: Martin Cartwright

Reviewer's report:

Major Compulsory Revisions

The Conclusion in the abstract claims that the evidence from the two trials suggest “modest beneficial effects”. This does not reflect the overall pattern of findings in the studies reported which observed only marginal improvements in the optimised condition. All but one of the NHST conducted were non-significant. By convention (various sources) even the greatest magnitude of OR reported here would only just reach the threshold for a ‘small’ effect in Cohen’s terms (usually taken to be somewhere around 1.5). The interpretation of the findings in the abstract is therefore skewed and overly positive. The author should adapt the language to reflect the overall pattern and scale of effects observed.

The authors should revise the first paragraph of the Discussion to give a more representative view of the overall pattern of findings, which were almost exclusively non-significant.

Minor Essential Revisions

The authors should provide some comment on the sample used during ‘user testing’ and the implications this has (e.g. for the effectiveness of the optimised materials in different clinical samples).

On page 12, the last three sentences that describe the randomisation process is a little unclear (especially with regards to “the first 25 eligible patients to complete this process at each practice were randomised”). The authors should clarify this process further.

On page 15 under Data Analysis, gender is introduced as a potential moderator variable. No prior rationale is provided for examining gender. The author should provide this rationale.

Discretionary Revisions

During the trial there was an administrative error in the Depression study such than individuals randomised to optimised patient materials, and who did not respond to the first letter, were sent the usual (non-optimised) patient materials as a reminder. This is a substantial deviation from the protocol and could have had a substantive effect on the findings. There are at least two potential
mechanism by which this could have affected the findings, and which pull in opposite directions. Explanation 1: the ‘dose’ of the intervention was effectively diluted and therefore differences between trial arms would be diminished. Explanation 2: the difference in patient materials between the first letter and the reminder could have operated along the lines of the Hawthorne Effect whereby change per se rather than the nature of the change (or content of the intervention) drive beneficial outcomes. These two alternative mechanisms have important implications for the interpretation of the trial, especially since it was in the depression study where the only significant p-value as observed. Without resulting to inferential tests, the authors could explore these two alternative explanations by examining the proportion of responders after the initial letter (across trial arms in the depression study) and comparing this with the reported proportions that represent the final response after initial (optimised) and reminder (non-optimised) letters were sent, compared to the control arms (non-optimised only). Differences in proportions at ‘time 1’ and ‘time 2’ might suggest whether it was the optimised materials or the change in materials that drove any difference between trial arms.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

No competing interests.