Author’s response to reviews

Title: Health services changes: is a run-in period necessary before evaluation in randomised clinical trials?

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Author’s response to reviews: see over
Dear Editor-in-Chief

RE MS: 1055540678107312 - Health services changes: is a run-in period necessary before evaluation in randomised clinical trials?

Many thanks for your suggestions to improve our manuscript. We have considered and addressed the suggestions in the manuscript and provide our responses below.

Reviewer: Derrick Bennett

1. Were there equal numbers of physiotherapists in each of the 4 PCTs included in the study?

There were 8 physiotherapists from each PCT (32 in total). The number of physiotherapists in each PCT has been entered on page 6 (line 127) of the manuscript.

2. For the results of the joinpoint regression model the authors should make it clearer what the equivalent time changes are for the mean change in slope values. For example, it was not immediately apparent that -0.21 (0.03) in Figure 2 is equivalent to a 12 second reduction in call time mentioned in the result section first paragraph.

On page 11, line 265, the sentence has been amended to make it clear that the reduction in call time of 0.21 minutes from Figure 2 is equivalent to 12 seconds. The footnote for Figure 2 on page 24 has been amended stating the change in call time in minutes and seconds between joinpoints.

3. If the run-period had insufficient power to detect equivalence between usual care and Physiodirect service how can the researchers be sure that the non-statistically significant difference during run-in between the interventions was not due to lack of power?

Because this is an equivalence trial the relevant issue is whether or not the 95% confidence intervals for the between-group difference overlap the between the pre-specified limits of equivalence. Even though the run-in period sample was obviously
smaller than that of the main trial and therefore the between-group difference had a wider confidence interval, the 95% confidence intervals for the between-group differences for both clinical outcomes lie entirely within the pre-specified limits of equivalence for both run-in and main trial phases.

4. Did the authors consider using a stepped-wedge design in order to implement the Physiodirect intervention?

A step wedge design may be appropriate for studies where the unit of allocation is a cluster. As PhysioDirect was designed as individually-randomised, it was not considered.

Reviewer: Stephen John Walters

The aims of this study were to: determine the optimal run in period of consolidation for new primary care service prior to the main RCT; to determine if the provision of a running period of consolidation was needed before patient and processed outcomes were evaluated.

1. The conclusion is a little weak and equivocal. The authors should be more explicit and unequivocal about whether or not a run-in period is required for health technology assessment; and if it is required in what circumstances.

The abstract (page 3, line 56-57) and the main conclusion of the paper (page 18, 430-431) have been amended. Future trials should build in a run-in period if it is anticipated that learning would have an effect on patient outcome.

The question posed by the authors is clear and well defined.

2. The methods are appropriate and reasonably well described. However the manuscript would be improved with a more detailed description of the patient reported outcomes and the join point regression analysis.

See below for points 5 and 6.

The data are sound and well controlled.

The discussion and conclusions are well balanced and adequately supported by the data.

The title of the paper in the abstract accurately convey what has been found.

The standard of writing is acceptable.

- Minor Essential Revisions

3. Lack of punctuation, i.e. full stops, after the statement of the aims of the paper on page 4.
Full stops have been added after the aims on page 4 (line 90, 92).

4. Page 9 - was the data analysed using a multilevel model? The methods section is not explicit in whether or not multilevel models were actually used. “Multilevel models were considered to model called time……..”. Does this mean multilevel models were used?

Multilevel models were used for this part of the analysis. The above sentence has been amended to reflect this on page 9, line 212.

- Discretionary Revisions

5. I am unfamiliar with joinpoint regression analysis as perhaps are many other readers of Trials. The authors may wish to expand their description of joinpoint regression analysis.

More information has been given on joinpoint regression analysis on pages 8/9, line 190-204.

6. Although I am familiar with the SF 36 and MyMOP patient reported outcome measures many readers of Trials may not be familiar with these outcomes. The authors may wish to expand their description of the SF 36 and MyMop in the methods section of the paper.

More detail has been reported on patient outcomes on page 7, line 160-166.

We have addressed the reviewers’ comments and we look forward to hearing from you at your earliest convenience.

Yours faithfully

Trishna Rathod