Reviewer's report

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

Version: 1 Date: 8 November 2013

Reviewer: Stephen John Walters

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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. The study concludes

“A run-in period of consultation was not needed in a large testing the children services in terms of patient. However, learning curve was evident in the process measure telephone call. Future trials could build in a running period and use similar methods described here to identify when designing stabilises.”

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 question posed by the authors is clear and well defined.

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.

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

Lack of punctuation, i.e. full stops, after the statement of the aims of the paper on page 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?

- Discretionary Revisions

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.
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.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

None