Author's response to reviews

Title: A Prospective Clinical Trial of Specialist Renal Nursing in the Primary Care Setting to Prevent Progression of Chronic Kidney: A Quality Improvement Report

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Version: 4 Date: 27 August 2014

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

On behalf of my co-authors, I re-submit for review and possible publication in *BMC Family Practice* the Research Article entitled “A Prospective Clinical Trial of Specialist Renal Nursing in the Primary Care Setting to Prevent Progression of Chronic Kidney: A Quality Improvement Report”.

We have fully addressed all of the concerns of the reviewers, and these are listed in a point-by-point fashion below.

We continue to feel that this work is an important piece. The report describes the evaluation of an alternative model of healthcare delivery utilizing a specialist nurse-led intervention in primary care to prevent chronic kidney disease progression and cardiovascular disease. The results suggest that a collaborative model of care such as this can improve patients’ self-management of risk factors for chronic kidney disease progression and cardiovascular disease, and improve well-accepted surrogate clinical endpoints.

I will serve as the corresponding author. In advance, thank you for your consideration.

Sincerely,

Mark R. Marshall, MPH FRACP
Associate Professor of Medicine
Reviewer 1

Major Compulsory Revisions

“Lower p-values than expected given 52 patients, 5 time points, and quite a degree of variability within the group”

For the mixed methods analyses, the statistical methods take full advantage of the internal correlation between repeated measures within patients - the variation within the group is of little relevance in this model, which essentially models the change within patients over time. This number of patients with 5 such measurements is a powerful dataset for inference. In clinical trials involving interventions to LV mass, frequently only < 100 patients are needed in the setting of only 2 repeated measurements\(^1,2\). The p-values are entirely as expected given the nature of the cross sectional time series, and the magnitude of observed changes.

Although reviewer 2 has had us remove them, the secondary statistical analyses of these outcomes also yielded estimates suggesting significant change over time, which is reassuring.

Minor Essential Revisions

1. Pg 7 line 4: “In this study, we present the results of this intervention in order to demonstrate the effectiveness of this model of care.” Please reword to reflect the fact that the study design is not able to reliably demonstrate effectiveness.

   Sentence reworded to “In this study, we present the results of this intervention in order to demonstrate the clinical potential for this model of care”

2. Pg 19 line 19/20: “There is no study in the literature that can be used to determine effect size between with improved self-management and improved clinical outcomes.” Delete “with”

Done, thanks.
Reviewer 2

Major Compulsory Revisions

1. Abstract Methods should include selection criteria, as these are important for interpretation of the results

Done, thanks.

2. Abstract conclusions – need to be softened to better reflect the strength of evidence which can be drawn from this study – ‘has the potential’ is too still too strong. Also perhaps ‘Further, larger, controlled studies’

Reworded as suggested, thanks.

3. Statistical methods. It is not clear why the so called secondary (incorrect!!) analysis is reported in the methods and table. It is not referred to in the text of the results so adds nothing to how the results have been interpreted and is inappropriate. It should be dropped from the methods (and table 3)

Dropped as suggested.

4. Discussion page 18 line 16 – too strong. As this was not controlled you can not even state it was associated. Reword – could say something like during the course of the nurse led intervention

Reworded as suggested, thanks.

5. Page 22 line 6 – sentence about regression to the mean. It is indeed very plausible that there was some influence of regression to the mean – this discussion needs to be strengthened (and the ‘less plausible’ removed). It should be explained in more detail that the selection criteria meant that those included were all at the extreme of the distribution of measures the same as or associated with many of the outcome measures and had been through a period of poor attendance to appointments. As this study is uncontrolled it is very likely that some of the improvement in measures observed was due to regression to the mean. It is reasonable to argue that the time period of severity of symptoms prior to selection may have reduced this effect but it remains a very definite, unquantifiable limitation on the interpretation of the results.

We agree, and have strengthened the wording around this limitation. With the reviewer’s permission, we have used some of his/her turn of phrase.

6. Conclusions – again has the potential to is too strong. Perhaps is feasible and may

Reworded as suggested, thanks.

7. Conclusion line 7 - ‘appears to’ is too strong

“Appears to” changed to “May be”

8. Table 3 drop last column (secondary analysis)

Done, thanks.
9. I was unable to see any reference to table 4 – is it required? If included it needs to be mentioned in the results

We believe this should be included, given the online format of the article. This is an expansion of the co-morbidity scoring of the patients, which was requested from us by the original reviewers. So long as there is no objection from the editorial staff, we would like to include it. We have mentioned it in the results, and clarified the legend.

**Minor Essential Revisions**

1. **P11, line 25 – missing word**
   Thanks, “which” added.

2. **Results – Correct Inconsistency of numbers on table and first line – table says 36 available at 12 months**
   Fixed, thanks.

3. **Discussion page 19 line 19, 20 – needs rewording**
   “with” removed as per Reviewer 1 comment.

4. **Conclusion second sentence needs rewording**
   “The cost of implementing such a program on a wider basis would be considerable, although costs maybe offset in the long-term if the future burden of ESKD is reduced.”

**Discretionary Revisions**

1. **Table 3 The number of decimal points reported in the p values is excessive and meaningless.**
   Fixed, thanks.
