Author's response to reviews

Title: Effectiveness of management models for facilitating self-management and patient outcomes in adults with diabetes and chronic kidney disease

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

Re: Effectiveness of management models for facilitating self-management and patient outcomes in adults with diabetes and chronic kidney disease

Thank you for the opportunity to re-submit an amended version of our protocol, “Effectiveness of management models for facilitating self-management and patient outcomes in adults with diabetes and chronic kidney disease”. We appreciate the reviewer’s comments and have made a number of changes to the protocol in light of the comments received. All changes made to the protocol are highlighted. Below is an itemised response to the reviewer’s comments and resultant amendments.

**Major Compulsory revisions**

1. Establishment of a conceptual framework or a logic model; - *A logic model has been established (Figure 1).*

2. Clarification of methods, “Adult patients (above 18 years) with diabetes and/or CKD”; - *The study will include adult patients with diabetes, kidney disease or both kidney disease and diabetes. Data will be analysed separately for these three groups. The title now includes ‘adults’ as well.*

3. Primary outcomes: a maximum of three outcome measures should be specified here; - *The protocol has been amended to include only three primary outcomes which are blood pressure, eGFR and HbA1c. We do not expect to find many studies reporting on diabetes complications and adverse events given the short duration of interventions (averaging 6 months).*

4. RCTs: EPOC criteria go beyond RCTs, for example investigate interrupted time series....I authors want to go beyond the RCT design they should clearly say so; - *The protocol now clearly states that only RCTs will be included for the study.*
5. Inclusion of studies: at least two reviewers should perform the initial literature scan; - Due to budgetary constraints, we are not practically able to have two reviewers performing the initial search. However, the first reviewer may consult with the second reviewer during full text review if in doubt and then the second reviewer will assess 20% of the retrieved articles for methodological quality.

6. Overall quality assessment: the GRADE instrument should be used; - The protocol has been amended to include the GRADE assessment (Table 1).

Minor Essential Revisions

1. Adherence to consistent terminology; - The protocol has been amended to consistently adhere to the terms ‘self-management model rather than self-management programmes’.

2. Abstract: instead of ‘all EBM’ better use ‘Cochrane Library...’; - We would like to continue to use All EBM Reviews because All EBM reviews contains additional articles that are not listed in The Cochrane Library and it is accessible via the Ovid searching platform where we are able to perform efficient and rigorous searching of multiple EBM journal databases at once.


4. Objectives: authors mention efficacy but title states effectiveness; - protocol amended to consistently mention effectiveness.

5. Methods: “Only studies whose chronic disease management models have included one or more of the above components will be eligible for inclusion.” So, if for example a study just provides materials to patients (‘patient education’) this would be called a chronic disease management programme? - Yes, it would be part/component of a self-management programme.

6. Secondary outcomes: 'Quality of life', should be health-related quality of life; - Protocol has been amended accordingly.

7. Search methods: 'all EBM' should just be called Cochrane Library; - Please refer to item 2 above.

8. Appendix 1: just a few comments focusing on MEDLINE:-

Line 16 should be constructed as line 12. – This has been amended as suggested.

Line 22 should read: eliminate one self monitor* - This term is an alternate presentation of self monitor/self-monitor and therefore we feel that it should stay in case of alternate spelling.
Line 23, 29, 30 and 41 appear to narrow (adjacent operator may be used) – We are confident that these text words will supplement the use of MeSH and broad terms.

Line 72: should be deleted because already established in line 61 – This line has been removed.

Line 51-57: if authors really want to include RCTs only the validated Cochrane strategy should be used – We are confident that the proposed filter will identify RCTs.

Line 41: should this not be part of block lines (1-3)? – We consider the block of lines 1-3 as population/condition terms, whereas line 41 is an intervention term, defined by the use/addition of the word ‘model’.

9. No search strategy for systematic reviews, meta-analyses, HTA-reports-Systematic reviews will also be searched by using a validated filter for identification of systematic reviews. Please refer to Appendix B.

10. Will authors search trial registers- The National Institute of Health Clinical Trials Register (https://clinicaltrials.gov/) and the Australian and New Zealand Clinical Trials Registry (http://www.anzctr.org.au/) will also be searched.

11. Figure 1: no information in blue rectangles (figure 1 is shown on page 9 and 17); - Information has been supplied. Please note that the figure number has now been changed from figure 1 to 2.

12. Assessment of methodological quality: the MCHRI template is a template for a general critical appraisal of an RCT (see template title) and not just a tool to assess methodological quality/risk of bias; - The MCHRI template allows us to appraise included RCTs for risk of bias and to outline issues of internal and external validity. We believe these factors are essential to evidence synthesis. The GRADE assessment will also be used.

13. Data analysis: anticipated use of a statistical meta-analytic model should not depend on the level of heterogeneity but should be established by thorough reasoning whether e.g. the assumptions of a fixed-effect model apply-We have amended the data analysis to read: “Pooled results will be analysed using a random-effects model, assuming a degree of heterogeneity among self-management trials being sought here.

14. Funnel plots investigate small study effects (not only publication bias) and should only be employed if 10 studies or more investigate a particular outcome (see Sterne JA, Sutton AJ, Ioannidis JP, Terrin N, Jones DR, Lau J, et al. Recommendations for examining and interpreting funnel plot asymmetry;- Protocol has been amended to reflect this.

We believe that the protocol has been enhanced significantly by the reviewer’s comments. Once again, thank you for the opportunity to re-submit the amended version of the protocol for consideration of publication in the Systematic Reviews Journal.
Kind regards,

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