Author's response to reviews

Title: Patient navigators for people with chronic disease: protocol for a systematic review and meta-analysis.

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Author's response to reviews: see over
January 20, 2014

Dear Editors,

Please accept our article entitled “Patient navigators for people with chronic disease: protocol for a systematic review and meta-analysis”, revised to address the reviewers comments. Each comment is addressed below and in the revised manuscript.

1. I notice that the authors distinguish navigators from peer support. They may wish to consider how they’ll handle patients trained to be navigators; the assumption that peer support is informal/unpaid is not always correct.

Response: It was not our intention to exclude formally trained peers, and we apologize if this was not clear. Patients or peer support persons will be included if they meet our definition of patient navigators, in that they are trained and their role is primarily assisting patients to overcome barriers to accessing care. We are not excluding patient navigators that have additional roles, such as support. This has been clarified in the Methods section of the paper.

2. How will studies with different comparators be grouped for analysis?

Response: If more than one comparator group is used, we will choose the usual care or least intensity arm for inclusion in the analysis. This text has been added to the methods section.

3. The outcomes are not clear, and there are quite a lot. Would outcomes for different diseases be grouped together for analysis or handled separately - would MI and diabetes complications appear in the same analysis, for example?

Response: We agree that the outcomes are numerous and broad and we have revised the methods to accommodate the range in potential outcomes. The outcomes will be grouped into categories reflecting their proximity to mechanism of action of the intervention. We have purposely kept these groupings broad so as to be able to include all relevant outcomes that may be reported. These are further described in the Methods section. Comments regarding the data synthesis methods are included below.

4. Which outcomes will be extracted when a study reports several measures of the same domain (e.g., morbidities associated with diabetes)?

Response: We are not limiting, a priori, the number of outcomes that will be extracted. However, the synthesis plans, described below, will depend on the frequency of reporting for specific outcomes.

5. Death is listed twice (and is not a morbidity).

Response: This has been corrected in the manuscript.

6. The same problem applies to the secondary outcomes - would the authors really group hospitalization and specialist visits?

Response: Please see our response to point 3.

7. The synthesis plans are also vague and leave a lot to be decided based on the data. It’s difficult to offer more substantive comments in this section given the lack of detail about selecting/grouping/handling the outcomes. I assume the authors mean to use SMDs rather than
MDs when there are multiple measures, but perhaps they would put different measures in different analyses?

Response: We apologise for the lack of specificity and we have revised the data synthesis plans accordingly. In order to facilitate our goal of a quantitative analysis of patient navigator programs across a predictably heterogeneous group of chronic diseases, we are planning a stepped approach to data synthesis as described in the methods section (and below).

...If three or more studies report the same outcome within a category, and there are no apparent unit of analysis errors (or intraclass correlation coefficient (ICC) data are available), traditional random effects meta-analysis will be conducted, using standard methods to account for cluster-trials as relevant. We will report relative risk for dichotomous outcomes and standard mean difference for continuous outcomes. For outcomes that do not meet these criteria but for which data are dichotomous and where there are three or more studies within a category, we will use a previously described quantitative strategy for reporting median effect sizes. For all other outcomes and circumstances we will use a narrative approach to data synthesis.

8. The use of meta-regression with (few?) studies of such variable conditions, outcomes, study designs, etc. seems farfetched, and the proposed methods are not well described.

Response: With the changes we have made to our proposed analyses, a meta-regression has been removed from the methods. Given that understanding the differential effects of patient navigator program attributes on effect sizes is a goal of this study, we will do exploratory analyses to investigate differences in outcomes based on specific subgroups of studies described in the methods. Any quantitative associations will be explored using non-parametric methods.

9. I don’t see the search strategies attached to the manuscript, and these should be included.

Response: Apologies, we had intended to attach it to the original submission. The search strategy has been attached as an appendix.

On behalf of all of the authors, thank you again for your consideration of this manuscript.

Sincerely,

Elizabeth J. Kelly