Reviewer’s report

Title: Design of the ZWOT-CASE study: an observational study on the effectiveness of an integrated programme for cardiovascular risk management compared to usual care in general practice

Version: 1 Date: 15 Jul 2019

Reviewer: Robert McKelvie

Reviewer's report:

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Summary

This is a revised version of a previous submission. This is an observational study. The primary aim of the ZWOT-CASE study is to investigate whether the execution of an integrated primary care programme for CVRM in general practice leads to a more favourable CV risk profile in patients with known CVD or at high risk as compared to usual care. The authors have responded to the previous comments. I still have concerns about the design because it seems unnecessarily complex. They seem overly concerned about the Hawthorne effect so they want to follow the patients along with the physicians not knowing they are being observed. I am not sure this concern is as great as they are suggesting. However, if there is this concern it may have been better if they randomized in a step wedge fashion the physicians that were agreeable to be involved with the integrated primary care programme and just delay the time the involvement of some of the practices would start. However, ultimately they would all finally be involved in the integrated primary care programme. The fact one group wants to be involved in the integrative primary care programme and the other does not, for whatever reason, would seem to set the study up for a great deal of potential bias. The design will also set up a situation where there potentially will be a great deal of missing data. However, this is a design paper and my comments should not detract from the quality of the idea for this study. I think the question is important and this type of management strategy should be properly evaluated. However, I do think the paper is too long and would benefit by decreasing the length by at least 25% or so.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.
Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Yes

**Are the conclusions drawn adequately supported by the data shown?**
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Yes

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I recommend additional statistical review

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Acceptable

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