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: 0 Date: 06 Sep 2018

Reviewer: Robert McKelvie

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Summary

This is a design paper outlining a study that will examine cardiovascular risk management based on a chronic disease care model. One group of general practitioners will have their patients involved in a cardiovascular risk management program and the other will have their patients get usual care. The primary outcome will be the effect of the integrated program of risk factor management on the major risk factors of systolic blood pressure and LDL-cholesterol. This is designed as a pragmatic trial comparing integrated care for CVRM to usual care.

Comments

This is an interesting concept that needs to be studied. Integrative care is an important model because it will provide consistent care to patients either without cardiovascular disease but the presence of significant risk factors or to patients with established CV disease. There are some comments made in the paper that I think need to have clarification.

1. There are 56 practices but 157 GPs, this must mean that in a practice there is more than one GP.
2. It was not completely clear whether the practices are randomized, or the patients are randomized.
3. How was it decided about which practices would start first in the program?
4. Would all practices finally be involved in integrated program?
5. Why was it not obligatory to have the PNs follow a specialized course in CVRM? By not making it obligatory wouldn't this potentially create an unequal delivery of the service?
6. In usual care it was stated that most PNs have had a basic training in CVRM. If that is the case it seems the PNs in usual care may be no different than many of the PNs in the CVRM program?

7. What was the rational for the age range of 40 to 80 years?

8. Apparently, the control group risk profile based on complete data on age, sex, smoking status may be missing. What impact will this have on the analysis.

9. How was the subgroup of patients selected for the study?

10. Is there an issue with practices choosing to do the intervention versus control? Does this potentially create bias?

11. Why is the actual inclusion of patients after one year of follow up? It seems they should be included at the beginning of the year. This seems confusing to me.

12. To me it is very confusing that the patients are not identified and informed of the study at the beginning. Also, it seems unusual that the GP is not informed until later. There may be concerns about the Hawthorne effect but if both groups are aware of being in a study this should be minimized or at least balanced between the groups.

13. The authors state the intervention group is selected from 17 GP practices and the controls from 9 GP practices. However, I thought all these practices were involved based on earlier statements by the authors. So, what does this mean? How were the practices selected and how many were selected?

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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