Reviewer's report

Title: The contribution of qualitative research in designing a complex intervention for secondary prevention of coronary heart disease in two different healthcare systems [ISRCTN24081411]

Version: 3 Date: 27 April 2006

Reviewer: Peter Murchie

Reviewer's report:

General

Thank you for asking me to review this paper. It is interesting and well written and in general I would support publication. I do believe that it adds to the growing literature on designing complex healthcare intervention and papers such as these are important to inform the development of intervention design methodology such as enshrined in the MRC Framework. I am concerned however that the authors review of the literature has not been exhaustive. I am aware of at least one directly relevant qualitative study on nurse-led clinics in CHD which is not even referenced. I also think that several revisions are required before the manuscript is suitable for publication and have listed these below. I was particularly interested in the data on differences in attitude engendered by the different healthcare systems. This is a real strength of the current study that perhaps the authors should make more of. The authors may also wish to consider using one of the may available checklists for reporting qualitative studies.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. Methods Page 7 (Setting)
The authors state that limited time and resources restricted the study to four general practices. It would be important for the authors to reflect in the discussion on how typical these practices were and what implications this may have on the conclusions drawn.

2. Methods Page 7 (Participant Selection)
The authors state that different patients were selected for the two phases of data collection. It would be important to know why this was so, since it could be argued that it may have been more appropriate to interview the same patients twice.

3. Methods Page 9 (Data Collection)
The authors describe using both interviews and focus groups. In this section the state that one of the reasons was that interviews facilitated access to respondents’™ views which may have been hindered in focus group discussion. I think this needs considerable explanation. What evidence is there that focus groups can be inhibiting? Also, why were all patient data collected by focus groups while staff data was collected by both focus groups and interviews. This confused me and needs to be explained and justified more fully. Did the authors verify the inhibiting nature of focus groups by comparing the transcripts of groups and interviews?

4. Methods Page 9 (Data Analysis)
Could the authors explain why they did not use a qualitative computer package (e.g NVIVO). Was this a resource issue or a conscious methodological choice?

5. Methods Page 9 (Data Analysis)
The authors state that there was consensus that data saturation had been achieved. How was this reached?

6. Methods Page 9 (Data Analysis)
The final paragraph describing the sociological theory of symbolic interactionism is very vague. I think this needs to be expanded to explain how the theory was actually relevant in this study. It may be useful to illustrate this with some examples of how the theory informed analysis in this study.

7. Results Page 11 Time and Money
There have been previous qualitative studies of nurse led clinics for CHD secondary prevention. Some of
the results have been strikingly similar. It is disappointing that the authors do not appear to have referenced this study since it strengthens some of their conclusion.

This paragraph does not sit well in the discussion and would more appropriately be included as results.

The authors state that the depth of information gathered through this qualitative work was not obtained from objective evaluations of aspects of the intervention through questionnaires administered to participant. Was this attempted? The authors do not make mention of these questionnaires elsewhere. If so, it needs to be stated and a couple of examples used to illustrate the point.

10. Discussion Page 23. Study Limitations
The authors suggest that this study is the pilot phase of a randomised controlled trial. I am a little confused by this since the authors have made reference to the MRC Framework. I think from the outset the authors need to be clearer on whether or not they are following the MRC Framework in this study. If they are they need to be clearer about what aspects of the study correspond to which specific phases of the framework. If they are not using the framework they need to state this and justify it.

I would restate my earlier point about how consensus of data saturation was achieved.

10. Discussion Page 24. Study Limitations
The authors state the data may also have been influenced by the characteristics of the researchers and their relationship with the respondents. They need to explain precisely why and in what way this influence may have occurred.

11. They state that the non-clinical background of the qualitative researchers emphasised their objectivity and was more likely to promote openness among respondents. This is a striking assertion and the authors cite no evidence to support this view. Are clinical researchers incapable of having objective and open discussion with research respondents? One might equally argue that non clinical researchers are not sufficiently aware of the clinical issues to conduct meaningful interviews. This is a controversial point indeed, and at the moment appears to be a unsupported and judgemental statement.

12. The next paragraph also causes concerns as the statements about focus groups are almost completely contradictory. What do the authors believe? Why did they feel it necessary to conduct separate interviews with receptionists and nurses. Did these interviews prove or disprove the hypothesis that some individuals are inhibited in focus groups? Furthermore, what were the discussions between the research nurse and the practice staff. Were these part of the focus groups or were they separate and different discussion not previously mentioned?

13. Page 25 Conclusions
I do not agree that this study confirms the contention of Gunn et al. This study will only be able to confirm Gunn et al's contention once the larger trial has been conducted and reported successfully. At this stage the authors have identified much to help them in designing this trial, but will only know the true value of this qualitative work once it has demonstrably helped them to run a successful RCT. I think the authors need to acknowledge this. Similarly, I think it is stretching a point to suggest that the study confirms funders should fund supportive qualitative work. Again this is a conclusion that could only fairly be made in the light of a successful RCT.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

I was concerned that the existence of the Heartwatch programme and the apparent substantial difference in structure of the RoI practices make an intervention suitable for both settings very difficult to achieve indeed. It might have been useful to include a paragraph or two in the results and discussion explicitly comparing the two systems and the consequent implications for the design of the intervention.

Discretionary Revisions (which the author can choose to ignore)

I would advise the authors to avoid describing their subsequent trail as definitive as they do in the final paragraph on page 24.
**Which journal?:** Not appropriate for BMC Medicine: an article whose findings are important to those with closely related interests and more suited to BMC Health Services Research

**What next?:** Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

**Quality of written English:** Acceptable

**Statistical review:** No

**Declaration of competing interests:**

I declare that I have no competing interests