Reviewer’s report

Title: Accrual and drop out in a primary prevention randomised controlled trial: qualitative study.

Version: 1 Date: 11 May 2010

Reviewer: Jonathan Graffy

Reviewer’s report:

This paper reports on qualitative interviews with people who attended a screening session for the host trial but opted not to participate, and also people who agreed to participate, but then withdrew. It draws on responses both groups, which are reported separately. It is worth noting that the sampling strategy did not include the much larger group who did not attend the initial screening session. In other words, the study reports on the perspectives of people who considered taking part in the research.

Reading the paper, I felt the data presented from the first group – who opted not to take part was more interesting than that from those who withdrew. Indeed the reasons given by the latter group – that they had a side effect of the aspirin, or changed their mind (often because they didn’t like taking the tablets) did not seem so surprising. There appeared to have been little analysis of the data from the second group – despite the fact that the researchers had both interview and focus group data, what was presented was essentially a report on the problems that participants reported.

I was uncertain whether the paper would work better if the authors were to limit the account to the 11 participants who opted not to participate, or whether they should develop the analysis to draw more lessons from across the two groups. They may wish to consider this further.

There were two points in the “Implications” which I thought were useful and should have been included in the main conclusions. (At present the conclusions in the abstract are rather general and self-evident). The text to draw on reads:

“Focusing on individuals for whom unrelated health problems or other circumstances are their priority at the time of recruitment, individuals who are keen to participate but decline due to such factors could be asked for consent for follow-up at a later date to ascertain whether participation is now possible. This may be useful in trials with long recruitment periods. For individuals who have concerns about particular procedural aspects of a trial, procedures could be put in place to encourage potential recruits to engage in discussion with a research nurse allowing them to express their concerns and explore possible solutions, and even making minor protocol adjustments in special cases.”

The methods section includes participation data for the main trial, but no data is presented on the participation rate for the qualitative study reported. Similarly no
numerical data is presented on dropouts form the main trial, although reasons
given by some of those who dropped out are given. Thus it was not possible to
assess whether the drop-out rate was a significant problem or not.

Minor comments:
I was not happy with the description of patients concerns (such as being scared
of needles) as “mundane”. This sounded pejorative and there should be a better
word.

There is a bracketed reference to the author’s PhD at the end of the method, but
I was unclear why it was necessary to discriminate that work as different from the
data in this paper. The reason for citing this reference needs to be clearer or it
should be dropped.

Level of interest: An article whose findings are important to those with closely
related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a
statistician.

Declaration of competing interests:
Yes. I have previously worked with the lead author.