Reviewer's report

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

Version: 1 Date: 16 May 2010

Reviewer: Valerie Shilling

Reviewer's report:

Recruitment and retention of trial participants is an important topic. The views and motivations of those who decline or withdraw are not well understood yet have great significance for the design of future trials. To this end, the paper adds valuable data on an understudied group.

Major Compulsory Revisions: None

Minor Essential Revisions:

1. Introduction: Page 3 line 17 sentence beginning "however, research has". The positioning of reference 4 is unclear. It should be moved to the end of the sentence as I assume that the authors are using it as a reference to double-blind placebo controlled trials? Could the authors please include an appropriate reference for healthy individuals taking part (or not) in preventive interventions (I assume ref. 4 is not supposed to be an example of this as well)? (See also discretionary revisions - Introduction)

2. Qualitative study: Page 4 line 17/18 replace one of the "individuals" with a different word

3. Recruitment: Page 5 the authors give the accrual rates for the AAA trial itself on page 4 but do not give accrual rates for the qualitative study, these should be stated. As the authors note, interview studies are subject to response bias anyway which is amplified by the opt-in methods adopted here. Accrual rates would give an indication of the strength of this bias.

4. Results: Page 6 Age - if using mean give standard deviation

5. Page 6 Median score for the DEPCAT would be more appropriate however if the authors wish to use mean then we need some indication of variance. It would be helpful to include a sentence explaining the 4 variables that contribute to the score

6. Page 8 Stopping trial medication: the first paragraph is unclear and needs rewriting. Were participants asked to pick from a list of reasons for stopping?

7. Discussion Page 11 line 7 how does reference 3 support this sentence which is about the current data? Should it be linked to the previous sentence?

8. page 11 line 20 query use of capital after colon in this context

9. Page 12 Implications lines 3-6 this is a very important point but is not clearly written so loses some impact
10. Page 13 line 17 word "experiences" should read "experienced"

11. Page 13 line 18 onwards. While I don’t argue with what this paragraph says, I can’t see how it is an ‘implication’ of the study, based on what is included in the results section. Are the authors suggesting that the respondents who had side effects were unaware that these were potential side effects of the aspirin or were not appropriately informed? If so, this does not come out in the results section. This seems to be a very general statement rather than an implication of this study.

Discretionary Revisions:

1. Introduction

The following reference would seem to have direct relevance to the topics being discussed as it is concerned with the motivations and misunderstandings of decliners and adequate information provision - although granted this is health related research rather than a trial; it would seem to be relevant.

Williams B, Irvine L, McGinnis AR, McMurdo ME, Crombie IK: When "no" might not quite mean "no"; the importance of informed and meaningful non-consent: results from a survey of individuals refusing participation in a health-related research project. BMC Health Serv Res 2007 7: 59

Also, as the paper talks about ensuring appropriate recruitment materials and processes that fully inform potential recruits of the risks and benefits of participation I am surprised that the authors have not included reference to:

Snowdon C, Elbourne D, Garcia J: Declining enrolment in a clinical trial and injurious misconceptions: is there a flipside to the therapeutic misconception? Clinical Ethics 2007, 2: 193-200

2. Results

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The two extracts (P2.11 and P2.5) relating to being prescribed aspirin or a contraindicated medicine do not add anything. They do not tell us anything about the respondents’ views/feelings about withdrawing from the trial. It is enough (and clearer) to just state the reasons in the text.

3. Results and Discussion

More could be made of this data. As it stands, the paper now seems rather descriptive and to some extent has the feeling of being ‘stripped out’ from a much richer data set. For example:

Page 7 the authors write that P3.1 said that he would have gone on the trial if he had been guaranteed to receive the placebo (the extract from the interview does not support this). This surely is an interesting statement with relevance to people’s motivations to participate (or not) in trials?

Similarly, page 8 extract from P2.3 "I feel like well I've let them down but at the same time your health does come first" Again, Is this something that comes up elsewhere in the data? Do people feel uncomfortable with saying no or withdrawing and what is the cause of this discomfort?
The paper does a good job of describing important reasons for declining and withdrawing from this particular trial but more could be made of the data to inform future trial design. As the authors themselves state there is very little evidence on these two participant groups and there is room to improve the paper for broader interest and to make the most of the data.

**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:**

I declare that I have no competing interests