Reviewer's report

Title: Trials and Tribulations of Recruiting 2,000 Older Women onto a Clinical Trial Investigating Falls and Fractures: Recruitment and Methodology of the Vital D Study

Version: 1 Date: 25 August 2009

Reviewer: Emma Scott

Reviewer's report:

This is a clear, concise report of the challenges encountered by many researchers recruiting to a large scale trial. It gives detailed insight into both the strategies employed by the recruitment team and the problems they encountered with each method. Comment is frequently made about the labour-intensity of each method, which is valuable knowledge for other researchers planning their recruitment strategies, but it would also be interesting to the reader to have some information about the costs and cost-effectiveness of each approach. I do not think that this is a necessary revision for this paper but may be a consideration for future papers. In general, this paper is well-written and requires only a few minor revisions before publication.

MINOR ESSENTIAL REVISIONS:

Methods, Recruitment, 6. Targeted mail outs (p6, para1) - the last sentence should read "These targeted mail outs were done USING the databases..."

Results, Withdrawn participants (p9, para2) - Please clarify whether the 226 women who withdrew includes the 59 who left the study prior to their first dose of study medication. This is not clear in either the text or associated table (4), although it appears from the flowchart that the 226 probably does not include the 59 early withdrawals.

Discussion (p10, last para) - The spelling of Garrett’s name is different in the text and reference list (reference number 17). Please correct whichever spelling is incorrect.

Table 3 - Based on the numbers given, I make the percentage of participants from Mornington Peninsula to be 23.0% and from Other to be 5.6%. Please confirm and correct. It would also be good to add another category at the bottom of the table to explain how the remaining 112 participants met the eligibility criteria outlined in table 1.

Figure 1 - The second box (oval) states "N=7204 Potential participants contacted" but from the information provided in the text it appears that at least 29,400 women were contacted from the mail outs alone. The wording needs to be amended to clarify that 7204 potential participants contacted the research centre / responded to the recruitment strategies. The percentages in the last box
(withdrawals) need to be reported in the same format as the rest of the flow diagram, i.e. to one decimal place: Active n=116 (10.3%); Placebo n=110 (9.8%).

DISCRETIONARY REVISIONS:

Background (p3, para1) - it would be useful to the reader to know the age range of the "oldest sector of the female population". Also, references 7-9 should be grouped together in one set of parentheses.

Methods, Recruitment, 6. Targeted mail outs (p6, para1) - did the use of multiple databases result in any potential participants receiving multiple invites? Was anything done to monitor or avoid this? If you monitored it, did it make a difference? This may warrant comment.

Table 1 - the formatting seems to have slipped a little and the text in the guidelines column is cut short in a couple of places. It is possible to guess what the text probably says but it would look better if it was properly formatted.

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