Author's response to reviews

Title: Healthy Hearts - a community-based primary prevention programme to reduce coronary heart disease

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Author's response to reviews: see over
Dear Editor

Further to our previous correspondence we have revised the article in response to the comments made by your reviewer.

The comments, and the changes made in response, are outlined below.

1. Comment by reviewer:
   1) Provide references which relate a unit change (ie 1% absolute risk) in FHS to a % change in the rate of CHD.
   2) If they cannot do so, then please remove the word 'significant' from all of the text and state that 'the clinical relevance of a < 1% absolute change in FHS is not clear'.

Changes made: We recognise the issue being raised by the reviewer and agree that the wording should be changed. We have used the phrase “slightly lower” in the results section. We have also added a sentence to the first paragraph of the discussion as suggested stating, “However, the clinical significance of a less than one percent absolute change in Framingham Risk Score is not clear.”

2. Comment by reviewer:
   3) Since they now state that they pre-specified FHS as the endpoint, what was their anticipated effect size, and did they achieve that effect size?

Comments: Our original ethics application referred to a systematic review (Ebrahim and Smith 1997) had concluded that the effect of primary prevention programmes was likely to be a less than 10% reduction in mortality and that a reduction of more than 11% in deaths from coronary heart disease could be excluded by his data. We had pilot data from 200 patients indicating that the average Framingham risk score of 13.05. We estimated that we could produce a 7% fall in this average score to 12.14. The reduction we achieve was slightly smaller than this (6%).

Changes made: A sentence has been added to the first paragraph of the discussion section stating, “Based on our reading of the literature, our aim was to reduce the average Framingham risk score by 7%. The reduction we achieve was slightly smaller than this (6%).”

Yours sincerely

Hugo van Woerden

Reference