Author's response to reviews

Title: The Heart Health Study - Increasing cardiovascular risk assessment in Family Practice for first degree relatives of patients with premature ischaemic heart disease: a randomised controlled trial

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Version: 6 Date: 23 June 2015

Author's response to reviews: see over
23/6/2015

BioMed Central Editorial

Dear Editor,

Re: MS: 1662569951558703

Research article
The Heart Health Study - Increasing cardiovascular risk assessment in Family Practice for first degree relatives of patients with premature ischaemic heart disease: a randomised controlled trial Nigel P Stocks Prof, Jessica L Broadbent Ms, Michelle F Lorimer Ms, Derek P Chew Prof, Philip Tideman Prof, Gary Wittert Prof and Philip Ryan Prof BMC Family Practice (Section: Service organization, utilization, and delivery of care)

Response to editorial questions

In response to your questions please see below and the amended paper.

1. “I was not asking you to provide detail or comment on those ineligible but to report whether the 347 hospitalised people assessed for eligibility represented all those hospitalized in the study recruitment period who were fit enough to be approached as per study protocol. There could have been selection bias if there were substantially higher numbers passing through who could not be assessed for eligibility for a variety of reasons.”

I can only speculate about how many patients could have been eligible to participate but were not approached. The wards are very busy and there are multiple research studies being undertaken at different times. People are moved between areas and may not be available to be approached at the right time. Most patients only stay for short periods and staff do not have time to document every patient and whether they have been approached/eligible for a particular study.

The research nurses involved took a systematic approach to recruitment and identified potentially eligible patients each day by being part of a ward round with clinicians (researchers). We have no reason to believe that there was any systematic bias in recruitment that favoured a particular type of patient - except as detailed in the inclusion/exclusion criteria. Clearly the findings are only applicable to the group meeting the inclusion criteria, in particular the necessity for the patient to have premature ischemic heart disease. I don’t think we can make a meaningful comment other than acknowledge that this is a potential shortcoming.

We have modified (highlighted text) the previously added paragraph (lines 384 - 391) to read –

We assessed 347 hospitalised patients for eligibility and randomized 144. Clearly many ineligible patients (137), those living in remote aboriginal communities (28) and their first degree relatives would have a different set of circumstances from those participating in a trial. In addition there were some hospitalised patients who were not approached because they were recruited for other trials or were on the wards at weekends or holidays. As with any other trial we have selected an eligible population for whom the results are applicable and we cannot make any inferences about the impact of the intervention on these other
groups who make up a substantial proportion of all PIHD patients and their relatives.

2. “The abstract conclusion still does not reflect the low uptake rate, which is an important conclusion and has an impact on the statement currently provided as the abstract conclusion. Your intervention does not “ensure that those at high risk can be targeted” because of this low uptake rate. It does improve detection of increased risk relatives which is good but it is not sufficient on its own to target all relatives at increased risk”.

In your previous email you requested I change 'what this study adds' which I did.

I realise that the editors are concerned about the apparent low uptake rate in the second stage of recruitment. Strictly speaking we should talk about low recruitment in relatives rather than implying that the intervention does not work - in those who were recruited the intervention did result in many more relatives having a CVD risk assessment - hence our conclusions. Notwithstanding this I have edited the abstract and hope the following will be acceptable.

Replace

Conclusion: This low cost intervention ensures that individuals who have a family history of PIHD and are at moderate or high risk of CVD can be targeted for early intervention of modifiable risk factors.

with

Conclusion: This low cost intervention demonstrates that individuals who have a family history of PIHD and are at moderate or high risk of CVD can be targeted for early intervention of modifiable risk factors. Further research is required to improve the uptake of the intervention in relatives.

3. “I think you may have misread my request to report CV risk as low rather than mild?”

I have now replaced 'mild' with 'low'. Interestingly the terminology is not consistent in the literature and guidelines, in fact we only used 'mild' because this was used in the risk factor calculator then used by GPs in Australia.

Regards

Prof Nigel Stocks