Letters

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The Fremantle Primary Prevention Study: a multicentre randomised trial of absolute cardiovascular risk reduction

Brett *et al* recently described a randomised trial of cardiovascular disease (CVD) risk reduction in three general practices.[1] Suboptimal trial design may be a substantial contributor of concern about the efficacy and cost-effectiveness of such primary prevention interventions by health professionals.[2] We are concerned that such shortcomings also feature in their study.

The study aimed to measure the effect on CVD risk of more frequent GP visits. The number of study visits actually received was not specified, and is crucially important. Based on a small sample, opportunistic group participants received clinically significantly more 'non-study' GP visits, ostensibly unrelated to the intervention but possibly not. Also, the study design did not allow an effect to occur between the final GP visit and data collection. Therefore, we estimate that they potentially compared a mean of 9.6 intervention group visits with a control group mean of 7.8 visits (and not 5 versus 2 visits, as claimed). Similar levels of care may explain a lack of between-group differences for the primary outcome.

Counselling provided was unclear. Apart from risk measurement and target specification, GP-counselling was simply deemed 'individualised' and 'offered as appropriate' — further details would be welcomed. No framework for behavioural change is specified, nor is any protocol for initiation or intensification of drug treatment, despite potential influence on outcomes.[2] A substantial practice nurse role is hinted at in the discussion section but never described.

We are also concerned by the authors' conclusion that 'the study demonstrates that absolute cardiovascular risk can be improved by primary prevention strategies'. This misinterprets minor (and occasionally significant) improvements to individual risk factors — there was no significant between-group reduction in overall CVD risk. The authors also conclude that a 'targeted approach using absolute risk calculators can be used in primary care to modify global CVD risk assessment' — given that risk calculators were employed for both study arms, it should not be implied that this was evaluated.

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2. Ebrahim S, Taylor F, Ward K, *et al*. Multiple risk factor interventions for primary prevention of coronary heart disease. *Cochrane Database of Syst Rev* 2011; **(1):** CD001561.

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Authors' response

Philpot *et al* have done no more than reiterate (albeit in more detail) what we have already described and discussed in the paper.[1] The study design as outlined in the methods clearly states that the Fremantle Primary Prevention Study was 'an open, prospective, pragmatic[2] randomised study in three practices' involving 1200 participants with the aim of absolute cardiovascular risk reduction.

We sought to examine our intervention in the real life situation of busy clinical practices. We clearly stated that the study designated five visits for the intensive group and two for the opportunistic group and for ethical reasons we placed no restrictions on routine attendances outside of planned study visits. We have no information on whether or not relative risk cardiovascular targets were discussed at unplanned visits. It is possible that the impact of the intervention on absolute risk reduction could have been more marked if visits were restricted.

Time constraints inevitably impact on busy GPs and practice nurses in clinical practice and need to be taken into account in the design of research studies. In our study, ethical practice necessitated that clinical judgements on the efficacy of introducing or altering pharmacological treatment, referrals to a dietician, exercise physiologist, or cardiologist, were at the discretion of the treating doctor. The practice nurses played key roles in recruitment, randomisation, and follow-up of participants.[3] Whether health promotion messages are effective or not would depend on who delivers the messages and how they are delivered.

Effective translational research in a general practice setting requires a pragmatic approach which inevitably leads to complexity of study design. We were pleased that so many patients engaged in the study and follow-up discussions suggest their enablement benefitted from the experience.

All research can be improved as none is perfect.

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