Reviewer's report

Title: Design of a RCT evaluating the (cost-)effectiveness of a lifestyle intervention for male construction workers at risk for cardiovascular disease: The Health under Construction study

Version: 1 Date: 18 October 2007

Reviewer: Gil L’italien

Reviewer's report:

General
The study has merit in that the authors purport to assess the impact of a lifestyle intervention on multiple factors related to CV risk. However, despite extensive detail as to the assessment of behaviors and risk, the manuscript is lacking in several important details; eg the appropriate quantification of the effect of the intervention; the lack of blinding; the dampening impact of co-interventions among the control group on the effect of the intervention.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1) You cannot base the assessment of risk (ie Framingham risk) compared to the average for age if there is no information on the diabetes variable; given the high risk status of the these patients, the absence of diabetes information will underestimate risk for a relevant percentage of these patients, biasing the comparison to average.

2) (page 5) adding information to the Framingham risk score from the PHS does not constitute a new risk assessment instrument unless it has been validated against some 'gold' standard.

3) The sample size estimate is based only on one of the measured endpoints (ie physical inactivity. The authors must comment on the anticipated effect size (ie deltas) for the other primary and each of the secondary measures, and the power available to demonstrate a difference between the control and intervention groups. Also see item 5 below (bias toward the null). It may be helpful to provide a table listing all endpoints and their anticipated deltas and power.

4) The blinding of assessors/investigators is incomplete. Since subjects know their status (control/intervention), there are no safeguards preventing them from informing assessors/investigators.

5) Co-interventions; motivated participants in the control group may adopt lifestyle changes of their own. The authors acknowledge this, but they do not provide some estimate of the impact of this bias toward the null on power and sample size.

6) The choice of intervention (smoking or energy balance intervention) by the
subject complicates the analysis; it is really two studies: one assessing the effect of a smoking cessation intervention and one assessing the energy balance intervention. The authors must again comment on the reduction in sample size and thus power in these intervention subset analyses; since there are two differing interventions, there must also certainly be different effect sizes for each of primary and secondary endpoints. These will impact the effect sizes differently.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

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:

Employee of Bristol-Myers Squibb, a pharmaceutical company which manufactures cardiovascular risk factor modifying therapies.