Reviewer's report

Title: The effects of Hartcoach, a life style intervention provided by telephone on the reduction of coronary risk factors: a randomised trial

Version: 2 Date: 26 March 2012

Reviewer: Jonathan Mant

Reviewer's report:

Thank you for asking me to review this protocol. You asked me specifically to respond to the following questions:

1. Will the study design adequately test the hypothesis? YES
2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing? MOSTLY - SEE BELOW FOR CLARIFICATIONS Requested
3. Does the manuscript adhere to the relevant standards for reporting and data deposition: if not, in what ways? MOSTLY - SEE BELOW
4. Is the writing acceptable? THERE ARE A FEW GRAMMATICAL ERRORS BUT THE ENGLISH IS SUFFICIENTLY GOOD THAT IT IS UNDERSTANDABLE

Major Compulsory Revisions

1. Please clarify what is the primary outcome. In the first paragraph of the methods, several primary aims are listed. The sample size calculation uses total cholesterol. It is ambiguous whether this is the sole primary outcome, or whether they have selected this purely for the power calculation.
2. Assuming that a single primary outcome has been selected, please justify why they have chosen total cholesterol. (If they have selected multiple primary outcomes, then this is methodologically inferior, and they would need to justify this).
3. Given the importance of centre effects that are acknowledged, it is not clear whether you are stratifying (and blocking) the randomisation by centre?
4. Please clarify under 'participants' how you will determine what constitutes a 'previous or current similar lifestyle intervention'. Many components of usual care might superficially be deemed to be similar.
5. What steps are you taking to ensure that your intervention is administered in the way you intend (intervention fidelity)? How are you measuring this?
6. It is important in trials such as this to accurately characterise the control care. How will you prospectively capture what care the control group actually receive?
7. Please clarify the analysis. Is your primary analysis the extent to which the binary targets in table 1 are achieved, or the mean change in risk factor (for non-binary outcomes such as BP and cholesterol)? If it is the latter, are you
comparing change in risk factor between 0 and 6 months between intervention and control, or risk factor status at six months adjusted for baseline?

8. It is not usual to formally test baseline differences for statistical significance. Are you really going to do this?

9. Table 1 does not detail how the measurements will be carried out. This is important, as there is considerable variability in several of these variables depending upon how they are measured. Please add to table one the relevant additional details. For example, for BP, what guidelines are being followed for measurement? What machines are being used? For cholesterol, which lab test is being used? How is waist circumference being measured etc etc?

Discretionary Revisions

10. Useful to add to the discussions potential limitations of the design. Eg: Patient not blinded - impact on measures which rely on self report; multiple outcomes - any adjustment (eg Bonferroni) being made? Even the objective measures are open to measurement error unless careful pre-specification about how they are performed;

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published

**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'