Reviewer's report

Title: Protocol for a randomised blocked design study using telephone and text-messaging to support cardiac patients with diabetes: A cross cultural international collaborative project

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Reviewer: Andrew Farmer

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Protocol for a randomized blocked design study using telephone and text messaging to support cardiac patients with diabetes: a cross cultural international collaborative project.

Thank you for asking me to review this protocol. The development of telephone and text-messaging to provide support for patients after leaving hospital is an important area of work. The authors have already developed an intervention, and now set out, in this protocol, their plans to evaluate the intervention in a multi-centre study in which the intervention is delivered in either English or Chinese.

The paper sets out the proposed detail of the trial. There are some references to revising and translating the CDSMP. However, these are not elaborated or detailed, and I wonder whether it might be easier to leave them out.

Compulsory revisions

The proposed research design is a 4-week impact of CDSMP compared with usual care on a range of self management/self-efficacy measures. It would be good to be clear about this. This is an explanatory short-term study that does not propose to measure clinical measures. Given that the authors wish to publish their trial protocol, they should specify a primary outcome measure or justify why they have not done so. This would be helpful in guiding the statistical analysis and avoiding the possibility of selection of significant outcomes after the analysis has been carried out.

The Background would benefit from some expansion. The authors have developed CDSMP, but I wanted to know more details. What is the content of the previous paper? What is already known about the effects of CDSMP? This study is funded by a research grant, so it is likely that there is already much text that could be added from the grant application to fill in the background details here.

A few more details are need in the method section. The allocation ratio is not specified in the text, although in the figure it is clear that it is intended to be 1:1.

The eligibility criteria may need revising. The first intervention is delivered while in hospital, but what happens if they then stay longer than 14 days. The criteria
need to be revised or the statistical issues associated with exclusion after randomization should be addressed.

More details of the CDSMP would be helpful. The paper referenced is a 20 patient randomized pilot study (10 in the intervention group, 10 in control). The study demonstrated small scale feasibility, but does not provide any more detail of the actual programme than presented in this protocol paper. More information about process (how many sms texts, what the training for nurses consists of, specifics of the intervention rather than just theory base, what is the text associated with reminders) would be helpful.

The sample size needs justification in greater detail, and in particular what constitutes a medium effect size for the primary outcome selected. I would suggest that 80% is a low power for a trial without data on which to base estimates of effect. Attrition of 28% is likely to introduce bias into the analysis and again reduce the efficiency of this study.

Details of randomization need describing in more depth, in particular the block size and the measures being taken to avoid subversion of the sequence that have been demonstrated with sealed envelopes. A state of the art randomization process would be preferable. Is an independent statistician involved in this process?

The statistical section needs much more detail. Is an ITT analysis proposed? Is there to be any adjustment for baseline values. Given that this is a multi-centre study, should this be taken into account in the analysis? The values from the chosen measures are likely to be skewed suggesting that a t-test might not be the most appropriate statistical test to identify between and within group differences. It might also help to discuss some prespecified sub-group analyses (e.g. is there an interaction between the impact of the intervention and language of delivery).

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Not suitable for publication unless extensively edited

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests