Reviewer's report

Title: Improving participation rates by providing choice on participation mode: Two randomized controlled trials.

Version: 2 Date: 10 November 2014

Reviewer: David Reeves

Reviewer's report:

Major Compulsory Revisions

Patient participation rates in primary care studies has progressively declined over the last ten years or more and the development of methods for improving participation is of growing importance. This paper makes a useful contribution to the literature on this subject. However, the statistical analysis is sub-optimal in not allowing for (a) a possible effect of host RCT trial arm on participation and (b) potential clustering of participation outcomes within practices (see below).

This was an observational study conducted within a cluster RCT of an intervention to improve cardiovascular risk management by nurses in general practices. Consent for the social network (SN) study was taken a baseline alongside consent for the RCT, but SN questionnaire/interview data was collected two months later, with the RCT follow-up at 6 months (ie 4 months later). Thus patients would have two months experience of the intervention at the time their SN data was collected. In addition, patients were not blind to the arm of the intervention they were randomised to. There is therefore a potential risk that a patient's participation in the SN study could have been influenced by their experience of the intervention or knowledge of trial arm. For example, patients not in the intervention arm may have been less motivated to provide SN data. Consequently the analysis of participation outcomes should ideally include trial arm as a covariate. Including trial arm would also reveal whether host RCT arm assignment in itself impacted on participation in the SN survey.

The RCT used practice as a cluster variable and took account of this in the calculation of sample size. The SN study randomised patients (to participation mode) within practices (ie used practice as a stratification variable) and did not adjust for clustering. It is a common misnomer to believe that randomising within practices removes the need to take clustering into account: in fact, it does not. If outcomes are clustered by practice, this will still affect the variance estimates associated with group comparisons. In the present case, the group difference in SN survey participation may well have varied non-randomly across practices. Therefore the analysis should ideally also adjust for practice clustering.

The present analysis is based on simple chi-square tests. To include the changes discussed above, of including host RCT trial arm as a covariate and practice as a cluster variable, a more sophisticated method would be required,
specifically logistic regression. The authors should either conduct an improved analysis or justify why they do not control for host RCT arm or adjust for practice clustering.

The paper needs a section detailing and discussing any limitations of the research. If the authors decide to justify their present analysis rather than refine it, that decision should be explained in the limitations section.

Minor Essential Revisions

A flow diagram, one for each trial, alone the lines of a Consort diagram, showing the flow of patients in each arm through the various stages of the study, would help readers to better understand what was done.

The use of English could be improved. There are a number of poor uses that are repeated frequently throughout the manuscript. Particular ones are:” telephonic interview” which should be “telephone interview”; “choice on participation mode” which should be “choice of participation mode”; and use of “was” when referring to a percentage, which should be “were” (eg “21% was willing” (21% were willing)).

Participation rate is specified as the primary outcome, but the results section presents results for Willingness to Participate (a secondary outcome) first. Results for the primary outcome should be given first.

Results; Trial 1; Willingness to participate. “In trial 1, less patients were…. would be better as “In trial 1, fewer patients were…."

Results; Trial 2; Participation rates. “lower than that of patient who” should be “lower than that of patients who"

Discussion, para 2. “Although this may be a limitation of this study….”. This sentence is not at all clear.

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

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

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

Declaration of competing interests:
'I declare that I have no competing interests'