Reviewer’s report

Title: Improving the outcomes of primary care attenders with common mental disorders in developing countries: a cluster randomized controlled trial of a collaborative stepped care intervention in Goa, India

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Reviewer: Andrew Vickers

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This is a nicely done trial and I would like to see the protocol be published. I have two comments.

1) It would be nice to see further details of randomization. In particular, I was looking for details of procedures that would ensure that randomization could not be interfered with. It seems possible, for example, that the statistician could misallocate a practice or a researcher change allocation later. To prevent this, you need some procedures. For example, what about something like:

The researchers randomly assign code numbers to each GP practice.

The list of the codes numbers is sent to the statistician, who assigns each code number to the intervention or control group

The statistician sends the list of code numbers and allocations back to the researchers

At the end of the trial the statistician's list and researcher's list can be reconciled to check that all practices were allocated as they should have been.

2) In the statistical analysis, I disagree with: "Any of the a-priori defined confounding factors for which randomization did not achieve balance between the two arms at baseline will be adjusted for". Such an approach is data dependent, and is not 100% reproducible (e.g. different statisticians might disagree as to what counts as an acceptable level of "balance"). Moreover, a variable that is predictive will improve statistical precision even if there is no imbalance. I therefore suggest that the authors write down a list of variables that they believe are likely predictive of outcome and then include those as covariates in the final analysis, irrespective of differences between groups or lack thereof. Incidentally, baseline mental health scores must go in the model, as doing so dramatically improves power (see Frison and Pocock, Stat Med 1992).