Reviewer's report

Title: Intervention to reduce excessive improve alcohol consumption & improve co-morbid outcomes in hypertensive or depressed primary care patients: two parallel randomised feasibility trials

Version: 2 Date: 27 March 2014

Reviewer: Natasha Cohen

Reviewer's report:

Previous comments were from myself and other reviewers have been addressed and accounted for. Many of the comments have been repeated amidst reviewers. I am unsure if the authors completely incorporated all the comments. For example, in ZS’s feedback, there is a question of how feasibility is defined, but there is no criteria set for determining feasibility per se. If none were used, it should be stated.

As well, I think that the question from LM “5. It is unclear why centres were randomized to hypertension or depression trial. What purpose did this serve?” may have been misinterpreted in that why would one divide these two processes rather than use the same clusters to study both the hypertension and depression question.

I commented on the need to separate primary and secondary outcomes as well as their respective analyses (major compulsory revisions, bullet 9). This issue was addressed by adding a paragraph

“The primary outcomes for each pilot trial were the rates of patient eligibility, recruitment and retention at 6-month follow-up. Secondary outcomes included those envisaged for a full trial (risk of alcohol use disorders, blood pressure and severity of depression) as well as acceptability of trial procedures to practitioners and patients.”

which is then followed by the descriptions of the measurement tools. This is not adequate, and the entire outcomes section should be divided into primary outcomes and secondary outcomes, with the measures used to assess these outcomes included in the appropriate heading and cutoffs described for success in the case of feasibility outcomes, which is still not included in this version of the manuscript and was mentioned in the initial set over revisions.

Moreover, sample size for both determining the number of clusters for the pilot study reported here and projected sample size remains lacking. Perhaps the help of a statistician may be necessary to obtain this calculation. This still needs to be better addressed and is mentioned in the major compulsory revisions included in my review.

Major Compulsory Revisions
Objectives – see comments above. Since this is a pilot study, feasibility-type objectives should be primary. Also, the objectives should not be included under the methods heading, and should rather follow the introduction.

In methods – need to explain how the sample size (i.e. number of practices) was identified as the target sample size. This also pertains to the statement of “At the second wave, recruitment targets had already been exceeded in the hypertension trial; practices approached were therefore invited to participate in the depression trial only”, which is likely based on a patient number sample size calculated, rather than cluster based. Please provide better justification for this in the methods section.

Analysis – need to mention the approach used to calculate a sample size for the larger study based on your findings. Also, should change the location of the sample size calculation result (number of participants and clusters needed) to the Results section and comment on the feasibility of doing the full study in the discussion. Also, it is unclear how the number of clusters were established, but it is important to remember that sample size should be calculated based on parameters derived from your own observations (i.e. need to calculate the ICC for each comparison, i.e. hypertension and depression, and use it for the calculation of sample size).

Minor essential revisions
P5 – introduction – there is an extra bullet with no text

“If at any point a respondent indicated a wish to withdraw from the study, they were thanked for their interest and not contacted any further. Any data collected on the patient to that point was retained” – were reasons for withdrawal assessed? If yes, please report.

Re: PHQ-9 “It has demonstrated 61% sensitivity and 94% specificity for detecting mood disorders in adults” – for which cutoff, since a range for inclusion is given.

“One hundred and twenty patients were sought at baseline (30 per arm per trial). This was based on a published recommendation for pilot trials randomizing by individual patient rather than by cluster [40].” This statement does not consider that fact that you have performed a cluster randomized controlled trial, which does not apply to the suggesting number of patients required in this recommendation.

Discretionary Revisions
“Most practices that gave a reason for declining indicated that they were too busy, or that the GPs were not interested” – give percentages if available.

Level of interest: An article of importance in its field

Quality of written English: Acceptable
Statistical review: Yes, and I have assessed the statistics in my report.

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