Reviewer's report

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

**Version:** 1  
**Date:** 16 December 2013

**Reviewer:** Zainab Samaan

**Reviewer’s report:**

1. **Title:** Minor Essential Revisions
   Please revise the title: “Intervention to reduce excessive alcohol…”

2. **Abstract:** Minor Essential Revisions
   Please revise text where sentences started with a number, e.g. “467(27%) of eligible patients returned”. Other examples are seen throughout the manuscript.

3. **Abstract and overall conclusion:** Major Compulsory Revisions
   “Recruitment and retention rates of eligible patients were higher in hypertension trial than in depression trial. A full trial of alcohol BI appears feasible for primary care patients with hypertension who drink excessively.”

4. **Major Compulsory Revisions**
   Both conditions of interest showed very low participation rates. Since no parameters of feasibility are reported, what was the basis for conclusion of feasibility in hypertension?

5. **Discretionary Revisions**
   Suggest to use “A tutorial on pilot studies: the what, why and how” BMC Medical Research Methodology, 2010, as a guide to structure the pilot study objectives and feasibility measures.

6. **The Study Objectives:** Major Compulsory Revisions
   “The objectives were to establish:
   - Numbers of primary care patients with hypertension or mild/moderate depression who were excessive drinkers (scoring 8 or above on the AUDIT tool) [39].
   - Rates of eligibility, recruitment and retention in trials of brief intervention versus information provision alone to reduce excessive drinking and improve health state in those two populations.”

   What are the expected rates that will be acceptable for the researchers to conclude a favorable outcome?
Acceptability to patients and practitioners of intervention and research materials and procedures.”

How was acceptability measured? What is a favorable outcome?

Feasibility of health outcome measures.”

How was this feasibility measured? What health outcomes are being tested for feasibility?

7. Methods: Minor Essential Revisions

Setting

Consider revising the text. The text seems difficult to follow and reach the final number of included practices and patients. Perhaps an overall summary and reference to the flow diagram are sufficient here.

8. Measures: Minor Essential Revisions

Why patients scoring >19 on the PHQ-9 were excluded from the study? Why exclude “severe” depressive symptoms?

9. Intervention: Major Compulsory Revisions

The authors stated, “Research staff received training in intervention delivery from an experienced alcohol interventionist (RM), who also observed the initial interventions in order to assess fidelity”.

How many interviews were observed, for what arm of the study? What is the effect of observing interviews on patients’ responses to questions?

10. Hypertension pilot trial: Minor Essential Revisions

Inconsistent reporting e.g. “Four hundred and sixty eight patients returned a questionnaire (27% of the 1,709 surveyed), including 4 who had not answered the AUDIT questions. Of these 467 respondents,

General Comments: Major Compulsory Revisions

11. The uptake by GPs and patients is very low, how feasible is it to introduce a brief intervention that is not acceptable by GPs? How will the intervention be delivered? By GP? What training will be required to deliver the intervention?

12. Please replace “gender” a social construct with sex, a biological construct.

13. Acceptability of procedures and materials

“GP practice staff and patients generally reported to the researchers that they found the research procedures acceptable.”

How were these opinions elicited and documented, what is acceptable?
14. Discussion

“This study provided evidence on the feasibility of a definitive trial of brief intervention to reduce excessive alcohol consumption in primary care patients with co-morbid hypertension or mild to moderate depression.”

This conclusion is not justified based on data and results from this study. The results of the study showed a very low participation and follow up rates and the trend for the intervention versus control procedures provided contradictory direction to the proposed hypothesis. It seems that proving information without the brief intervention is beneficial:

“Among participants whose systolic blood pressure had been above 140 mmHg at baseline, 21% of those in the control arm and 17% of those in the intervention arm had a reading below 140 mmHg at follow-up. Among participants whose diastolic blood pressure had been above 85 mmHg at baseline, 13% of those in the control arm and 11% of those in the intervention arm had a reading below 85mmHg at follow-up.

In the depression trial, 8% of participants in the control arm reported AUDIT scores at follow-up that were below the cut-off for hazardous drinking (7 or less); none of the 7 participants in the intervention arm scored below this cut-off at follow-up.”

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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