Reviewer's report

Title: Screening and brief interventions for hazardous and harmful alcohol use among hospital outpatients in South Africa: results from a randomized controlled trial

Version: 3 Date: 21 January 2013

Reviewer: Simon Coulton

Reviewer's report:

Many thanks for the opportunity to review this manuscript. The manuscript reports the results of a randomized controlled trial of screening and brief intervention for hospital outpatients in South Africa.

Some aspects of the study reporting are rather challenging and I have identified some areas where clarification is required, some of these are relatively minor and some quite major. I have addressed any issues in the order they arise in the manuscript.

Abstract

Some consistency in the use of terms to describe the nature of the population is required in the manuscript and throughout the paper generally. In the abstract the population of interest is described as hazardous and harmful alcohol users in the background, problem drinkers and medium risk drinkers in the methods. The time period recruitment occurred should also be reported as should the outcomes used. It is worth noting that the study reported is a RCT of alternative interventions, differences between groups are the primary statistic of interest rather than changes within groups and these should be reported with confidence intervals. (Minor changes).

Methods

In the design section the study is described as an efficacy study, previous, in the last sentence of the background, it is described as an effectiveness study. It needs to be clarified whether efficacy or effectiveness is being addressed in this study (minor).

It would be useful to have the hypotheses clearly stated as null hypotheses (minor). The last sentence under design is not necessary (minor).

In study population and participants it would be useful to know over what period outpatients were screened and whether all outpatients over this period were screened. Some of the text becomes quite repetitive and this would benefit for being more explicit in what happened and how it was conducted (minor). Under exclusion criteria a score of 20 or more on AUDIT indicates possible alcohol dependence rather than probable, it is a screening not a diagnostic tool (minor).
Under randomization more detail on the randomization procedures would be useful, were they stratified? Were blocks used? You have exactly the same numbers in either group and as a reader I would want to know that the allocation was conducted appropriately. (minor)

Under measures indication of primary and secondary measures are required, the Cronbach’s alpha of AUDIT is not necessary in this section (minor).

In the data analysis section it is not clear whether any data transformations were undertaken in testing the baseline descriptives, it is clear from the table that some of these outcomes were not normally distributed. I am not convinced that testing for differences between the groups at baseline is necessary, it only tests for those outcomes measured and if these differences are potentially influencing the observed outcome they need to be incorporated into the analysis of the primary outcome (minor). I would expect a sample size calculation presented in this section with an indication of clinically meaningful differences (major). GLM repeated measures were employed to assess the primary outcome at 12 months, AUDIT score, is this appropriate? I would have thought that considering the loss to follow-up at month 6 this would make any such analysis under-powered (major).

When looking at the results reported I had a number of major concerns. You assessed 1500 for eligibility, 1106 were excluded, leaving 394 for randomization into two groups. Each group had 192 so 10 patients are missing from the CONSORT statement. I also note that in the baseline demographic table few of the variables add up to 192 and some, for example education and AUDIT categories add up to 196. In the text under results we are informed that 194 were allocated to each group. There is a major discrepancy in how the results have been reported and this needs to be addressed (major).

Your primary outcome is AUDIT score and the primary analysis is the mean difference in AUDIT score between the control and intervention group at 12 months post-randomisation. This should be analysed using analysis of covariance adjusting for baseline values of AUDIT, as they will have greatest influence on 12 months AUDIT score. It is also likely that the AUDIT score would need to be transformed in order to conduct the analysis, it is rarely normally distributed in populations such as this. This statistic presented with estimates of the precision, such as 95% confidence intervals, is the most important finding. What we have is a cursory sentence that the intervention effect on the AUDIT score was -1.5. This is not acceptable for a study reporting a RCT and needs to be addressed (major).

As reported it is quite difficult to consider the conclusions as valid. The authors really need to consider what and how they are reporting the outcomes of this trial. Of particular concern is the lack of integrity in the numbers reported, the lack of a sample size calculation and significant issues in how the analysis has been undertaken and reported.
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: No conflict of interest