Author's response to reviews

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

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Author's response to reviews:

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: 4 Date: 8 April 2013

Reviewer: Simon Coulton

Reviewer's report:

Many thanks for the revised version of the paper and it is much improved. There are still a couple of issues that may mislead a reader and I think it is worth addressing them prior to publication

1. The hypothesis is not stated as a null hypothesis, while this may appear pedantic what is written cannot be tested using the methods applied, you can only find a null hypothesis to be untrue and as such the hypothesis should be stated as such. They is no difference in terms of AUDIT score at 12 months between control and those receiving brief intervention. The null hypothesis for the study was that neither brief alcohol intervention nor provision of health education leaflet will have a significant effect in reducing alcohol consumption.

R: Below is added

The null hypothesis for the study was that neither brief alcohol intervention nor provision of health education leaflet will have a significant effect in reducing alcohol consumption.

2. In the revised data analysis section it states that differences between groups was conducted using Mann-Whitney U-test for continuous data and chi-square for categorical data, but later in the same paragraph it states ANCOVA and logistic regression were employed, this is contradictory.

R: This is corrected by adding “baseline” differences, as below
Mann-Whitney U Test for continuous data and chi-square for categorical data were used to examine baseline differences between groups.

3. The study is described as an efficacy study but it looks more like an effectiveness study, 15% of those allocated to brief intervention received less than 13 of the 15 requisite intervention steps. So members of the intervention group were analysed as members of this group irrespective of the actual intervention delivered.

R: This is changed to effectiveness study; in cases of 15% who received less than 13 intervention steps, this does not mean they did not get the intervention; all got the intervention

4. On page 10 two different ITT assumptions were tested, these are not ITT assumptions but missing data imputations. One including all available data and the second imputing missing data.

R: Response as below

The analyses of the primary outcome measure were repeated using two different missing data imputations.

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

Version: 4 Date: 12 April 2013

Reviewer: Natalie Johnson

Reviewer's report:

Major Compulsory Revisions: 1. Methods (Sample size calculation) – May be incorrect. Until this point in the article, I thought the study outcome was a continuous variable (ie., AUDIT score). This calculation suggests that the outcome variable is categorical (ie., proportion of participants whose AUDIT score reduced).

R: Below is added to clarify

20% reduction in AUDIT score

2. Discussion (First para, second sentence) – In view of the results, the conclusion should be that “Self-reported outcome data suggests that screening and provision of a health education leaflet can reduce levels of hazardous and harmful ….”? and could be discussed in relation to similar findings, albeit in the primary care setting, reported by Kaner and colleagues (BMJ 2013;346:e8501) recently: http://www.bmj.com/content/346/bmj.e8501.pdf%2Bhtml

R: Corrected as below

Self-reported outcome data suggest that screening and provision of a health education leaflet can reduce levels of hazardous and harmful alcohol use in those patients attending a public hospital in South Africa. Similar findings, albeit in the primary care setting, have been reported by Kaner et al.[22].

Minor essential revisions:
1. Abstract (Results) – The first sentence seems incomplete. Perhaps it should read: “Of the 1419 screened for alcohol misuse who agreed to participate in the trial, 392 (27.6%) screened positive for hazardous or harmful alcohol use on the Alcohol ….”?
R: Corrected accordingly

2. Abstract (Conclusion) – The first sentence in the conclusion seems odd given that it follows a sentence saying the intervention was statistically non-significant.
R: First sentence is removed.

3. Introduction (Para 1, last 2 sentences) – Data on the proportion of adults in the general population who screen positive for hazardous or harmful drinking or possible alcohol dependence would aid comprehension of the information provided on the prevalence of these among outpatients in South Africa.
R: Below is added
In a national adult population-based survey 9% screened positive for hazardous or harmful drinking or possible alcohol dependence in the general population and 31.5% among current drinkers [9].

4. Introduction (Para 3, first sentence) – A reference regarding the number of outpatients treated in South Africa would be preferable here.
R: Below is added.
In South Africa the hospital out-patient utilization per person per year has been 4.2% in the general population [17].

5. Methods (Measures) – The word “use” is missing from the name of the AUDIT but as it has been described in full already, the abbreviation “AUDIT” is sufficient.
R: Corrected

6. Methods (Measures) - The cut-points for hazardous drinking (ie., 8-19 in men and 7-19 in women) should not overlap with the harmful drinking category (ie., 17-19). Based on my understanding of the AUDIT, the cut-points for hazardous drinking are 8-15 (and would be 7-15 for women using your approach) and 16-19 for harmful drinking.
R: Thanks, corrected as below
AUDIT scores higher than 19 indicate more severe levels of risk; scores of 8-15 in men and 7-15 in women indicate hazardous drinking and harmful drinking (AUDIT score 16-19).

7. Methods (Measures) – I’m still not clear when the primary outcome is assessed – is it at 6 months or 12 months (perhaps they are co-primary outcomes)?
R: Below is added
The AUDIT was assessed at baseline, 6 and 12-month follow-up.

8. Methods (Data analysis) – The phrase “6-month recall for alcohol use” seems odd. Is it meant to refer to the AUDIT or some other measure?
Differences between conditions were examined at the 6- and 12-month follow-ups using 6-month recall for alcohol use of the AUDIT.

9. Results (Participant characteristics) – Why mention levels 2 and 3 here when they have been omitted elsewhere?
R: levels 2 and 3 have now been removed

10. Discussion (Study Limitations) – I would prefer that the main outcome be described as “hazardous or harmful drinking” not “alcohol use” as the latter seems inconsistent with the information obtained from the AUDIT.
R: Changed accordingly

11. Discussion (Study Limitations) – Blood alcohol level is unlikely to be useful in this context.
R: This is removed

12. Discussion (Conclusion) – Insert “or harmful” after “sample of hazardous ...”.
R: added

13. References: There is a typo in the title of reference 4, the title is not boldface type in reference 7, the title of reference 22 is only partially in boldface type.
R: Corrected