Author's response to reviews

Title: The SHEAR study: protocol for a randomised trial of brief intervention for alcohol misuse for people attending sexual health clinics.

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Version: 2 Date: 13 July 2012

Author's response to reviews: see over
Changes made to the manuscript in regards to the reviewers’ comments:

1. Abstract and Introduction - the authors say there have been increases in levels of both harmful alcohol drinking and rates of sexually transmitted diseases – it would be useful to quantify this in more detail.

   We have added an update reference which provides more detailed information about rising rates of STDs in the UK during this period.

2. The protocol would benefit from being clearer about what activities and behaviours comprise unprotected sex, e.g. vaginal, oral, anal (receptive or insertive), and specifically getting information on the partners (to understand better the sexual networks)?

   We agree with the reviewer’s point and have provided the additional information that was requested.

3. The authors should justify more clearly why they chose a simple yes/no for whether the participant had unprotected sex - following on from the point above naively it would seem there may be valuable information in the number of partners, the frequency of unprotected acts, and their riskiness? Some of these are recorded as secondary outcomes.

   The following data are collected from participants at the time of follow up:

   - Total number of sexual partners during the last three months
   - Any incidence of regretted sex in the last three months
   - Number of people they had unprotected sex with (anal or vaginal sex without a condom) in the three months before the interview
   - Any incidence of unprotected sex while drunk in the last three months
   - How long they knew their last sexual partner before they had sex with them
   - Unwanted pregnancy in the last three months
   - Any new diagnosis of a sexually transmitted infection in the last three months

   We also specifically ask the participants about the last person that they had sex with and these include:

   - The gender of the person
   - How long they knew them before they first had sex with them
   - If they were drunk when they had sex with this last person
   - If they used condom the first time they had sex with this last person

4. It looks like to be eligible the participant needs only one episode of heavy drinking - so a man could be eligible with 1 night of drinking with 9 units, but somehow who say drank every other day and had 7 units each session (and had unprotected sex with a different partner once a week, say) would consume over 10 times the volume of alcohol and not qualify? Ok so perhaps it’s an unlikely example but nonetheless the definition seems to be very much about getting any possible excess drinking session included?
We accept that by using Modified Single Alcohol Screening Question (M-SASQ) we may have missed some potentially eligible participants. However we decided that it was important to use an approach to screening which was transferable to clinical practice outside the context of the trial. For this reason we selected a validated single item screening question which is recommended by the Department of Health and is widely used in clinical settings.

5. Background - the authors provide a thoughtful summary of the association between alcohol and STD - but are there any studies which directly asked people whether they thought that drinking was responsible for their STD?

We are aware of one study which found that over a third of participants indicated that their attendance at a sexual health clinic may be related to their use of alcohol. We have added a reference to this study to the paper.

6. The authors state that collectively the 3 sexual health clinics in London serve a diverse population - but they should discuss the limitations too e.g. this study may not be informative about rural drinking and STD, or drinking and sex in different cultures and settings with different socioeconomic levels than London?

We agree with the reviewer and have made the changes to the manuscript to acknowledge this limitation.

7. Does the participant need to be sober at the point of recruitment? Presumably that would be an exclusion criteria?

Our experience with SHEAR study is that patients do not attend the clinic whilst intoxicated. However, we cannot rule out the possibility of participants drinking prior to attending the clinic.

8. Although there is a 3 month contact, it doesn’t look like there is any attempt to get any interim outcome data? Given the later discussions about loss to follow up, isn’t this possibly a missed opportunity?

We did not have the resources to collect detailed follow-up data at three months. Previous trials of brief intervention for alcohol misuse that have generally used six month follow-up data to examine their impact.

9. How was the figure of £15 honoraria arrived at? Was this the maximum allowed by Ethics?

The Figure of £15 was based on consultations with various stakeholders including service user members of our project advisory group.
10. The authors should explain why having screened the participants with the short form, they don't then do the Form 90 at baseline on those randomised since it is the Form 90 that is used at the 6 month outcome assessment? Wouldn't this make for a more precise measure of the treatment effect (on reduction of alcohol)?

We agree that using a more detailed screening tool such as Form 90 would provide a more accurate assessment of current drinking patterns. However two factors led us to use a much shorter screening tool at the baseline interview. Firstly, to test the impact of a brief intervention delivered by front-line clinicians we needed to complete the baseline assessment between the point when people arrive at the clinic and when they see the treating clinician. This meant that we could not undertake a lengthy assessment.

However, more importantly we wanted to minimise the extent to which people in the control arm of the trial were asked to think about their alcohol consumption. Results from previous studies indicate that asking people detailed questions about how much they drink may lead them to reflect on and reduce their consumption. By keeping the assessment of alcohol consumption to a minimum we are maintaining treatment as usual for control patients who would not normally be exposed to detailed questioning about alcohol consumption in this setting.

11. Not many trials find themselves in the happy position of over recruiting. But how was the 'practical' size of 380/arm - over double the original size - arrived at? Was any of the accumulating data used? Does the trial have an independent Data monitoring Committee, and if so, where they involved in this redesign?

We only achieved this due to high levels of support from staff at clinics where we recruited participants. Baseline data from the first 200 randomised participants showed that 65% of them had at least one episode of unprotected sex in the six months prior to recruitment. We calculated that if 65% of participants had unprotected sex in the control group compared to 50% in the intervention arm, the power to detect such an effect would be above 90%, assuming 25% drop out, and a clustering design effect of 1.15. The power would remain above 80% if the absolute difference is 13%. The decision to increase the sample size was made with full agreement and support from the Trial Independent Data Monitoring Ethics Committee, Trial Steering Committee as well as the funder.

12. The discussions around missing data are reassuring, but isn't it almost certain that the data that are missing will be in the main part from a non-ignorable mechanism or mechanisms?

We agree with the reviewer's comment that missing data could possibly be non-ignorable. The best measure against this is to minimise the non-response, and this is why measures limiting attrition (such as monetary incentives) have been implemented. This is also why we want to explore in sensitivity analyses how the results may change under different assumptions about the possible outcomes in the non-responders. This will be an important part for discussing the findings, and indeed may add weight to the inferences if results are
broadly similar under a wide range of assumptions regarding the missing outcomes. However these approaches do rely on unverifiable assumptions about the missing data mechanism, and hence a sensible and more objective approach for the primary analysis is to assume an ignorable missing-data mechanism.

13. The authors say 'recruitment is ongoing'- could they be more specific- how many to date?

We have added further information about progress with recruitment to the study in this revised version of the paper.