Author's response to reviews

Title: A feasibility pilot trial of screening and brief alcohol intervention to prevent hazardous drinking in young people aged 14-15 in a high school setting protocol (SIPS JR-HIGH)

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Author's response to reviews: see over
Author's covering letter for initial submission

Title: A feasibility pilot trial of screening and brief alcohol intervention to prevent hazardous drinking in young people aged 14-15 in a high school setting protocol (SIPS JR-HIGH)

Authors:

Version: 1 Date: 22 August 2012

Comments: see over
Dear sirs,

Please find below our comments in relation to the reviewers report on our manuscript. Please let me know if there is any other information that you need.

**Title:** A feasibility pilot trial of screening and brief alcohol intervention to prevent hazardous drinking in young people ages 14-15 in a high school setting protocol (SIPS JR-HIGH)

**Reviewer:** John Norrie

<table>
<thead>
<tr>
<th>Reviewer's revision</th>
<th>Author's comment</th>
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<tr>
<td><strong>1. Safety</strong> – this looks like an ultra-low or no risk study, but for completeness it would be useful to have a sentence or two on safety. A couple of issues might be covered:</td>
<td>No response needed</td>
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<td>1a. The exclusion criteria specify that anyone already getting treatment or advice for alcohol related issues will be excluded – but what if the screening identifies a serious problem (e.g. drinking 3 or more units every day) which is a new discovery and is not getting any treatment – will the research team refer such a person for counselling/treatment?</td>
<td>The screening instrument is filled in anonymously however young people are given information leaflets which gives details of support services locally (added to the manuscript). If a young person is eligible for the trial and a Learning Mentor was worried or concerned about a young person they followed their normal school policies and procedures in relation to support (page 12).</td>
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<td>1b. What if a child who is perhaps already vulnerable – mentally or socially – is upset by taking part in the research project, and gets concerned about alcohol and the risky behaviours discussed? Is there any way this could be detected and then acted upon?</td>
<td>The young people are given an information leaflet which gives details of support services locally (added to manuscript). Furthermore if Learning Mentors were worried or concerned about a YP they followed their normal school policies and procedures (page 12).</td>
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<td><strong>2.</strong> The authors describe this in various different places as a ‘pilot’ trial, a ‘feasibility trial’ and a ‘pilot feasibility trial; pilot and feasibility are generally not well defined or differentiated, but there is a useful definition on the NIHR website (<a href="http://www.netscc.ac.uk/glossary/#glos6">http://www.netscc.ac.uk/glossary/#glos6</a>). It would be helpful to stick to one – this does seem to be a pilot/feasibility type design?</td>
<td>The reviewer is correct this is a feasibility pilot trial and the manuscript has been changed to reflect this.</td>
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<td><strong>3.</strong> The objectives of the pilot and what will be learned about the design of a future definitive RCT are well articulated, with the possible exception of specific issues about the cluster design. A couple of issues:</td>
<td>No response needed</td>
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<td>3a. The authors could be more detailed about how they are going to use the pilot to estimate the intraclass correlation coefficient.</td>
<td>Although an estimate of the intraclass correlation coefficient can be calculated from the pilot trial data, it will be very imprecise given the small sample size and number of clusters. We will therefore be looking to get more reliable estimates from similar published studies.</td>
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<td>3b. And there is little mention of contamination, either from the learning mentors or from the children and/or their families sharing the intervention. On the learning mentors, training them all in the same location on the same day might increase the possibility of contamination, perhaps?</td>
<td>Randomisation is at the school level (page 7) to reduce the chance of contamination. Learning mentors were only trained in the condition they were randomised too (page 12 under the heading Training and Support).</td>
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<td><strong>4.</strong> The Level Two intervention will only take place if ‘the young person consents to parental involvement and parents subsequently agree to take part’ – but does this take place after randomisation just for those who are randomised to this arm, or was this assessed for everyone, regardless of randomised arm? The former could lead to differential post randomisation exclusions in just this arm? How was this handled?</td>
<td>For level 2 cases, the young person was entered into the trial on an intention to treat basis (by agreeing to the level one intervention) and then were asked if they agreed to parents being contacted – this has been clarified in the manuscript.</td>
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<td><strong>5.</strong> The authors state that recruitment will take place until May 2012 – so what is the current status i.e. has recruitment been completed?</td>
<td>Recruitment finished in July 2012. This manuscript was sent to the journal in April and we have been awaiting a response since then which has mean that we have now finished recruiting.</td>
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