Reviewer's report

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)

Version: 2 Date: 16 August 2012

Reviewer: John Norrie

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Discretionary revisions

The authors present a very clear protocol on what looks a fascinating trial of a complex intervention of an important question. There are just some minor queries & comments:

1. Safety – this looks like an ultra low or no risk study, but for completeness it would be useful for the authors to have a sentence or two on safety – couple of issues might be covered:
   a. 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?
   b. 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?

2. 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 (http://www.netscc.ac.uk/glossary/#glos6). It would be helpful to stick to one – this does seem to be a ‘pilot/feasibility’ type design?

3. 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 – couple of issues:
   a. The authors could be more detailed about how they are going to use the pilot to estimate the intraclass correlation coefficient
   b. 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?

4. 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?

5. The authors state that recruitment will take place until May 2012 – so what is the current status i.e. has recruitment been completed?