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The development of a multi-centre individual-randomised controlled trial of screening and brief alcohol intervention to prevent risky drinking in young people aged 14-15 in a high school setting (SIPS JR-HIGH)


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Abstract

Background
Young people are vulnerable to the effects of alcohol consumption. Adverse impacts from alcohol manifest in a range of short and long term physical and psycho-social factors, including neurological issues, cognitive impairment, and risk-taking behaviours. The aim of the multi-centre SIPS JR-HIGH individual-randomised controlled trial (RCT) is to evaluate the effectiveness and cost-effectiveness of alcohol screening and brief intervention to reduce risky drinking in young people aged 14-15 in the English high school setting.

Methods
Building on the mixed method cluster randomised controlled pilot feasibility trial (10/3002/07), the proposed sample for the definitive trial, to be conducted from September 2015 until December 2017, has been calculated to have a 90% power and will follow-up 257 young people in each arm at 12-month follow up. To recruit this sample, twenty schools will be recruited (September 2015), with five schools recruited from North East England, the North West, London and Kent. The individually randomised two armed RCT will incorporate a control arm of usual school-based practice on alcohol issues and an intervention arm which combines usual care with a 30 minute brief intervention delivered by school learning mentors. Individual pupils will be randomised to one of the two arms. Descriptive statistical analysis will be used to report the pupil-level baseline data, with multiple linear regressions being used to compare the primary outcomes between the two arms at 12 months.

Findings
The pilot trial guided the development of the manualised intervention, which includes process information and a 30-minute personalised interactive worksheet-based session delivered by learning mentors. The pilot suggested that this intervention was acceptable, however an intervention with parental involvement was not found to be feasible, with parents not engaging with the research.

Interpretation
Limited evidence exists in a UK context to explore screening and brief intervention to reduce risky drinking in young adolescents. The pilot trial has informed the design of the upcoming definitive trial which, if the intervention is effective, will facilitate the development of manualised screening and brief intervention to be adopted in routine school practice in high schools in England.
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Contributors
All authors contributed to the design and development of this feasibility pilot trial. ELG and DNB drafted this abstract and all authors read and approved the manuscript.

Conflicts of interest
We declare that we have no conflicts of interest.