A multicentre RCT of screening and brief alcohol intervention in young people aged 14-15 in secondary schools: SIPS JR-HIGH RCT

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Conflicts of interest

Professor Eileen Kaner was a funding board member of the NIHR Public Health Research funding board when this grant was awarded and is Deputy Chair of the NIHR Postdoctoral Fellowships panel and is a co-applicant on the NIHR School of Public Health research, NIHR School of Primary Care Research and NIHR Innovation observatory.

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Professor Luke Vale is a panel member NIHR HTA CET panel, was a panel member for the NIHR PGfAR (2008-2015), and is Co-Director NIHR Research Design Service North East.

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Scientific summary

Background: In 2016, 11% of girls and 9% of boys aged 11-15-years-old reported consuming alcohol in the past week. Alcohol consumption also increases throughout adolescence, with 1% of 11-year-olds reporting drinking in the last week, increasing to 4% of 15 year olds. This is against a backdrop of the Chief Medical Officer's recommendations that young people should not drink alcohol before the age of 15 years; those aged 15-17-years-old are advised not to drink, but if they do drink they should do so no more than once per week. They should also not exceed adult limits in any given week, and ideally should be consuming alcohol below this level.

Alcohol screening and brief interventions (ASBIs) have been shown to be effective in reducing alcohol consumption in young people. Brief interventions have been around since the 1970s and focus on providing one-to-one feedback on individual's alcohol behaviours, of short duration, and often are based on the principles of motivational interviewing, delivered by non-specialists.

There is currently a lack of evidence on the effectiveness of one-to-one ASBI to reduce risky drinking in young people, particularly in a UK (United Kingdom) secondary school setting. However, evidence from other countries suggests that ASBIs has a positive impact on alcohol-related outcomes in young people. This study built on the SIPS JR-HIGH pilot feasibility trial which found that it was feasible and acceptable to deliver ASBIs to young people in a UK secondary school setting; it aimed to establish the effectiveness and cost-effectiveness of the intervention.

Objectives:

1. **To conduct an individually randomised controlled trial to evaluate the effectiveness and cost-effectiveness of alcohol screening and brief intervention for risky drinkers compared to standard usual practice on alcohol issues conducted by learning**

mentors with young people aged 14-15 in the school setting in the North East, North West, South East and London, England.

2. **To measure effectiveness in terms of percentage days abstinence over last 28 days; risky drinking; smoking behaviour; alcohol-related problems; drunkenness during the last 30 days; and emotional wellbeing.**
3. **To measure the cost-effectiveness of the intervention in terms of quality of life and health state utility; QALYs; Service use costs and cost-consequences at 12-months post intervention.**
4. **To monitor the fidelity of alcohol screening and brief intervention delivered by learning mentors in the school setting.**
5. **To explore barriers and facilitators of implementation with staff.**
6. **To explore young peoples experiences of the intervention and its impact upon their alcohol use.**
7. **If the intervention is shown to be effective and efficient to: develop a manualised screening and brief intervention protocol to facilitate uptake/adoption in routine practice in secondary schools in England.**

Methods: This study assessed the effectiveness and cost-effectiveness of an ASBI to reduce alcohol consumed by young people, in an individually randomised controlled trial within a secondary school setting. It was informed by a prior three-arm parallel group cluster randomised (with randomisation at the level of school) pilot feasibility trial with young people aged 14-15-years-old in Year 10 across seven secondary schools in the North East of England. Thirty schools were recruited into the trial across four sites in England: North East, North West, Kent, and London. The research included a qualitative evaluation with school staff (teachers and learning mentors), young people, and parents to explore the acceptability of and implementation of the ASBI, and acceptability and feasibility of wider trial procedures and processes in the school setting. Individuals were randomly allocated with equal probability to one of two trial arms: the control arm in which they received a healthy lifestyles information leaflet only; or the intervention arm in which they took part in a 30-minute one-to-one structured intervention session based on motivational interviewing (MI) principles with a member of

trained school staff (learning mentor) and received an alcohol leaflet. To assess eligibility for the trial, the young people completed a baseline survey (unless their parents opted them out). If they screened positive on a single alcohol screening question (A-SAQ) and left their name and provided informed consent, they were randomly allocated to the control or intervention condition. At 12-months post-intervention or control, a follow-up survey was undertaken, including the same measures as at baseline in addition to the Timeline Follow-Back. The primary outcome measure was total number of standard drinks consumed (units), where one standard drink equates to eight grams of pure ethanol, in the last 28 days, as measured using the 28-day Timeline Follow-Back.

Results - Objectives 1-3: Eligibility for the trial: In total, 4523 young people completed the baseline survey. Of these, 1064 screened positive (24%) for risky drinking on the A-SAQ.

Recruitment into the trial: In total 443 young people (just under 10% of all those surveyed, 42% of those screening positive) were eligible to take part in the trial by scoring positive and leaving their name to be contacted to participate.

Control: In total 223 young people were allocated to the control arm.

Intervention: In total 210 young people were allocated to the intervention arm.

Follow-up: At 12-months post-randomisation 374 (84%) young people completed a follow-up survey and 368 (83%) completed the 28-day Timeline follow-back to report on the primary outcome measure. Of those in the control arm 196 (88%) were successfully followed up, compared to 178 (85%) in the intervention arm.

Findings: The median values of the primary outcome (total units consumed in previous 28 days) were 7.3 in the intervention arm and 7.7 in the control arm. Quantile regression indicated that there was no difference in alcohol consumed by young people at follow-up between those who did and did not receive the intervention (Intervention – Control: median total units of alcohol in past 28 days 0.8 (95% CI -2.5 to 4.0)). Findings: The results showed no significant difference between trial arms in terms of alcohol consumed at 12-months after delivery of the intervention/control sessions. Quantile regression indicated that there was no difference alcohol consumed by young people at follow-up between those who did and did not receive the intervention (Intervention – Control: median total units of alcohol 0.8 (95% CI -2.5 to 4.0)). Economic analysis suggested that the average net cost saving of the brief intervention was

£1324 (95% CI: -£5277, £1727) per year compared to usual practice (results excluding costs of missed school days), with a 77% probability of the intervention being more cost-effective than usual practice.

Results - Objective 4: Training of 80 learning mentors across schools in the four sites was undertaken in order to prepare them for delivering the control and intervention sessions with the young people in the school setting. To assess fidelity, recordings were undertaken of sessions delivered with some young people.

Recordings: In total, 18 recordings were made, seven control sessions and 11 intervention sessions. The control sessions were considered to have adhered to the protocol if no mention of alcohol was made during the session. All of the intervention sessions adhered to the protocol.

Fidelity: The Behaviour Change Counselling Index (BECCI) was used to measure fidelity of the brief alcohol intervention. BECCI is a tool developed to measure the microskills of behaviour change counselling and motivational interviewing. BECCI ratings were given on a range of 0 to 4 to different items on a checklist, where: 0 = 'not at all', 1 = 'minimally', 2 = 'to some extent', 3 = 'a good deal', and 4 = 'a great extent'. Scores on the 11 intervention recordings ranged from 0.3 (behaviour change counselling delivered 'not at all') to 2.5 (behaviour change counselling skills delivered 'a good deal'). The mean BECCI score for the 11 recorded interventions was 1.6 and the median score was 1.5; these ratings suggested that the learning mentors overall were delivering behaviour change counselling to 'some extent'. Learning mentors typically performed well when discussing the risks associated with the young person's alcohol use. Lower scores were observed in respect of microskills relating to discussing and exploring behaviour change.

Results – Objectives 5 and 6: School staff interviews: In total 30 interviews were undertaken with school staff; 21 learning mentors and nine teachers.

Five key themes were identified: 1) learning mentors' understanding of alcohol use by young people, and of their role in delivering alcohol screening and brief interventions; 2) initiating and sustaining alcohol screening and brief interventions; 3) factors influencing successful delivery of the trial; 4) the impact on staff and young people; and 5) embedding intervention into routine practice.

Results: School staff perceived that components of the intervention were similar to some of the pastoral work that they already undertook within the school around alcohol, although the intervention more strongly emphasised alcohol use compared to their usual practice. The intervention was perceived to be acceptable, with the intervention sheet in particular being thought of as a very useful tool for engaging young people in discussions around alcohol. This sheet included what the young people were drinking, who with, what they think about their drinking, what they think other people feel about their drinking, and goal setting in relation to their drinking. The learning mentors who delivered the intervention and control sessions felt that they were well-prepared for delivering the sessions and that the preparatory training that they had received was well planned and thorough. A few learning mentors indicated that they would have liked refresher sessions where there had been a time lag between training and the intervention period.

Young people interviews: In total 33 interviews were undertaken with young people (n=7 intervention; n=10 control; n=16 negative A-SAQ/not randomised).

Three key themes were identified: 1) drinking identities and awareness of risk; 2) access to support and advice in relation to alcohol use; and 3) appraisal of the study and potential to impact on alcohol use.

Results: Young people indicated that they thought that secondary schools were an acceptable setting in which to conduct alcohol screening and brief interventions with young people who may be drinking alcohol at risky levels. They perceived the survey to be easy to complete and understand, and also found the intervention worksheet to be a useful tool for engaging them in discussions around alcohol. However, some young people felt that the gap between participating in different elements of the intervention and follow-up was too long, for example in some cases there could be months between the baseline survey and the intervention or control sessions. Additionally, there was some doubt around the impact that the intervention would have on their alcohol use, with only a minority of young people explicitly stating that they had reduced their alcohol consumption as a consequence of receiving the intervention. There was an overall perception that the intervention could be useful for 'other' young people who drink more than them.

Parent interviews: In total two interviews were undertaken with parents.

Results: Given the poor recruitment of parents to take part in an interview, there were limited data to analyse. However, the two parents who participated agreed that school was an appropriate setting in which to deliver an alcohol intervention to young people; and that whilst alcohol use is declining in young people, interventions such as this remained important to inform young people about the dangers of consuming alcohol.

Results - Objective 7: The intervention was not found to be effective.

Conclusions: The results showed no significant difference between arms in the trial on the effectiveness of ASBI with young people. That is there is no clear evidence about the mechanism which might drive cost savings. This raises doubts as to whether any cost savings would be real or an artefact of imprecise cost data. Interviews with school staff, young people, and parents found that they were largely accepting of the trial procedures and processes, that they perceived learning mentors to be an appropriate person to deliver the ASBI in a school setting, and that the intervention itself was a clear and informative way to inform young people about their drinking behaviours.

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