A pilot feasibility cluster randomised controlled trial of screening and brief alcohol intervention to prevent hazardous drinking in young people aged 14–15 years in a high school setting (SIPS JR-HIGH)

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Scientific summary

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Background

Alcohol consumption increases throughout adolescence. Approximately 33% of 15- to 16-year-olds in England report alcohol intoxication in the past month, with adolescents in the UK being among the heaviest young drinkers in Europe. It is recommended that children should abstain from alcohol before the age of 15 years, and those aged 15–17 years are advised not to drink, but, if they do drink, it should be no more three to four units and two to three units per week in males and females, respectively, on no more than 1 day per week. Only a few primary prevention programmes to prevent underage drinking have reported positive outcomes. Thus secondary prevention, i.e. targeting interventions at young people who are already drinking alcohol, is likely to be a more effective strategy, as the intervention will have more salience for the individuals receiving it. Alcohol Screening and Brief Interventions (ASBIs) have been shown to be effective in reducing alcohol consumption in young people. Brief interventions (BIs) generally focus on individuals' beliefs and attitudes about a behaviour, their sense of personal confidence (self-efficacy) about changing it and how an individual's behaviour sits in relation to other people's actions (normative comparison). Given the well-documented parental influences over adolescent alcohol use, interventions that aim to involve parents, which enhance parents' awareness of the variables and strategies that can delay onset and reduce consumption levels in their child, offer an opportunity for limiting the harms of adolescent drinking; however, mixed effects have been found to date.

There is currently insufficient evidence to be confident about the use of ASBI to reduce excessive drinking and/or alcohol-related harm (risky drinking) in younger adolescents and in a school setting. Nevertheless, the current evidence base suggests that the most effective forms of ASBI are those containing personalised feedback about a young person's drinking behaviour and motivational interviewing (MI) approaches to help reduce levels of alcohol-related risk. Furthermore, there is some evidence to show that involving parents in ASBI may be beneficial; however, the evidence is limited. This work builds on the evidence base by focusing on ASBI to reduce hazardous drinking in younger adolescents (aged 14–15 years).

Objectives

1. To conduct a three-arm pilot feasibility cluster randomised controlled trial (cRCT) (with randomisation at the level of school) to assess the feasibility of a future definitive cRCT of ASBI in a school setting.
2. To explore the feasibility and acceptability of ASBI and trial processes to staff, young people and parents.
3. To explore the fidelity of the interventions as delivered by school-based learning mentors.
4. To estimate the parameters for the design of a definitive cRCT of brief alcohol intervention, including rates of eligibility, consent, participation and retention at 12 months.
5. To pilot the collection of cost and resource-use data to inform the cost-effectiveness/utility analysis in a definitive trial.
6. To develop the protocol for a definitive cRCT and economic evaluation of the impact of brief alcohol intervention compared with standard advice to reduce alcohol consumption.

Methods

This study assessed the feasibility of a cRCT of the effectiveness and cost-effectiveness of ASBI (in a school setting) to reduce hazardous drinking in adolescents. A three-arm parallel group cluster randomised (with randomisation at the level of school) external (rehearsal) pilot feasibility trial in young people aged 14–15 years in Year 10 at seven secondary/high schools across one local authority area of North East England was carried out. The trial ran in parallel with a repeat cross-sectional survey, three times in the same year group and at the same schools, which facilitated screening [case identification for the trial at the first time point (time point 1, TP1)]. It included an integrated qualitative process evaluation with a key stakeholder (school staff, young people, learning mentors and parents), which examined barriers and facilitators to the use of ASBI in the school setting with this age group. Schools were randomly allocated to one of three conditions: feedback that young people were drinking in a way that may be harmful and provision of an advice leaflet (control condition, $n =$ two schools); a 30-minute brief interactive session, which combines structured advice and MI techniques delivered by the school learning mentor (intervention 1, $n =$ two schools), as well as the feedback and an advice leaflet; or intervention 2, which consisted of intervention 1 plus the offer of a second 60-minute session involving family members delivered by the school learning mentor (intervention 2, $n =$ three schools). Participants to the trial were young people who screened positively on a single alcohol screening question [Adolescent Single Alcohol Question (A-SAQ)], left their name on the questionnaire and gave consent. Measures included the 10-question AUDIT, which measures risky alcohol use. Adult cut-off scores of 8+ and young people cut-off scores of 2+ on the AUDIT were used to measure risky drinking. The European Quality of Life-5 Dimensions (Youth version) (EQ-5D-Y) and a modified Short Service Use Questionnaire (S-SUQ) were used to inform health and social resource costs for any future economic evaluation. At the 12-month follow-up, young people recruited to the trial met with the learning mentor and randomly completed the A-SAQ and AUDIT. The 28-day Timeline Followback (TLFB) questionnaire – a retrospective interview to ascertain the actual amount of alcohol consumed over the 28-day period prior to the interview – was also completed.

Results: objective 1

The study succeeded in recruiting seven schools as planned. Results showed that the study presented direct benefits to participating schools in terms of boosting alcohol education provision through additional staff training and the provision of enhanced support for participating students in need. The screening and consent procedure produced sufficient young people to rehearse the trial procedures.

Results: objectives 2 and 3

Interviews were carried out with six school lead liaisons, 13 learning mentors, 27 young people and seven parents (total $n = 53$). The school was found to be both a feasible and an acceptable environment in which to intervene with young people who are risky drinkers. Learning mentors were seen as appropriate members of staff to carry out the interventions.

Training

The study showed that it was possible to train learning mentors in the research requirements (consent/intervention delivery) and the training was seen as appropriate by learning mentors.

Screening

Overall, the screening survey was found to be feasible. Teachers were often present, overseeing the class while the young people completed the screening survey. Delivering training to teachers regarding informed consent and the importance of enhancing and maintaining confidentiality is likely to improve the overall acceptability of the screening survey.

Intervention 1

Intervention 1 was found to be feasible and mostly acceptable. There was some hesitation among learning mentors around informing young people whose drinking placed them at risk. The calorie-focused content also resulted in mixed views from both young people and learning mentors, and we have therefore decided not to include this within a definitive study.

Intervention 2

Intervention 2 was not feasible to deliver. Parents and young people did not express a desire or benefit in engaging in this intervention. Learning mentors, parents and young people questioned the utility of an intervention that they believed was not engaging the 'right' people. Although the parents who did engage in intervention 2 found the intervention to be acceptable, it should be noted that most invited young people and their parents did not participate in this intervention. Some of the young people interviewed told us that they did not want their parents involved. Furthermore, the literature around parental involvement is equivocal, with no clear indication that involving parents in interventions to reduce their children's drinking is effective.

Fidelity

The Behaviour Change Counselling Index (BECCI) was used to measure fidelity of the delivery of interventions by the learning mentors, and the results suggest that the learning mentors delivered the behaviour change counselling aspect of the intervention to an acceptable level.

Results: objective 4

Eighty-seven (6%) parents opted their child out of participating in the study. Discussions with young people and parents indicate that many of these parents thought that they were opting their children *into* the study. A total of 1280 (92%) young people completed the baseline survey and, of these, 229 (18%) met the eligibility criteria of reporting drinking at least four times in the last 6 months on the A-SAQ and left their name on the questionnaire. At baseline, 497 (39%) young people screened positive for risky drinking (A-SAQ) but only slightly over half of them left their name and so were contactable regarding participation.

Survey

Of those who completed the question at TP1, 629 (50%) of the sample were male and 1189 (94%) were white. The prevalence of smoking rose from 242 (20%) at TP1 to 300 (25%) at time point 2 (TP2) and reduced to 261 (23%) at time point 3 (TP3). The median number of days that young people reported physical exercise was four at all three time points. The median number of daily portions of fruit and vegetables was two each per day at all three time points. The proportion of young people who reported drinking alcohol fewer than four times in the last 6 months (A-SAQ) was 497 (39%) at TP1, 576 (47%) at TP2, and 541 (47%) at TP3. The proportion of risky drinkers using the AUDIT adult cut-off score of 8+ rose from 313 (26%) at TP1 to 344 (29%) at TP2 to 369 (32%) at TP3. Using a young person cut-off score of 2+ the prevalence rose from 699 (58%) at TP1 to 777 (66%) at TP2 to 798 (69%) at TP3. The differences in all measures between TP1 and TP2 were significantly different but not between TP2 and TP3. Between the first two surveys, the median scores for AUDIT increased by two units, but there was no change in median scores between the second and third surveys. General psychological health was measured using the Warwick–Edinburgh Mental Well-being Scale (WEMWBS), which gives a score of between '14' and '70', with a higher score indicating a higher level of mental well-being. At TP1 the median score for general psychological health using the WEMWBS was '48'. The Rutgers Alcohol Problems Index (RAPI) was used to assess alcohol-related problems; possible scoring range is 0–69, with higher scores indicating more problems. The median score for the RAPI at TP1 was '2'. A total of 602 (50%) individuals scored '0', and three (0.3%) scored the maximum of '69'. The comparison between subgroups at baseline demonstrated that gender, smoking and sexual behaviour were significantly associated with young people's current drinking behaviour. We found very low rates of missing data for all variables.

Trial

Learning mentors recruited 182 (79.5%) young people who were eligible for the pilot trial. This recruitment rate matched that which we had anticipated (approximately 79%). Only 23 (10%) young people did not consent to the study. A further 24 (10%) failed to meet with the learning mentor to discuss the trial for a number of reasons, including repeated absence, school exclusion and the existence of complex behavioural needs.

Control

Of the 60 young people who were eligible for the trial, three (5%) did not meet with the learning mentor and five (8%) did not give consent. In total, 53 out of 60 were recruited (88%).

Intervention 1

Of the 79 young people who were eligible for the trial, 15 (19%) did not meet with the learning mentor and 10 (13%) did not give consent. In total, 54 out of 79 (68%) were recruited.

Intervention 2

Recruitment to the intervention 2 arm was higher than expected. Of the 90 young people who were eligible for the trial, seven (8%) did not meet with the learning mentor and eight (9%) did not give consent to intervention 1. In total, 75 out of 90 (83%) were recruited and received intervention 1. Of the 75 students recruited into this arm, only eight (11%) received both the individual intervention (intervention 1) and family intervention (intervention 2).

Follow-up

Once enrolled in the trial, 160 (88%) of trial participants provided data at the 12-month follow-up meeting with the learning mentor. This was a higher rate than we had anticipated (65%). The pilot trial has achieved the goal of demonstrating that outcome measures could successfully be collected in a high proportion of participants.

Results: objective 5

There were very low levels of missing data in the use of health-economic tools (3.4–3.9%), with EQ-5D-Y being seen as an appropriate tool. The majority of young people indicated that they had no problems on the first three dimensions. Higher levels of problems were found in the last two dimensions of pain or discomfort [235 (19%) having some level of problems] and being worried, sad or unhappy [301 (24%) having some level of problem]. This indicates that there is some opportunity for the definitive trial to improve health, at least in terms of the final two dimensions (pain and discomfort). We found between 4.2% and 4.8% of answers missing at baseline in relation to service use. The majority of young people reported no use of services [except general practitioner (GP) visits]. The use of open-format diaries meant that differing levels of data were reported by learning mentors, especially in relation to preparation time. This enabled identification of the categories that were needed for a definitive trial.

Results: objective 6

For a future definitive study we propose a four-region, two-arm cRCT (randomisation at school level), with integrated economic and process evaluations. Young people who screen positive for risky drinking and give their consent will be randomised to either of the following groups:

A control condition Standard alcohol advice in Personal, Social, Health and Economic Education (PSHE) lessons delivered by class teachers, as well as feedback that they may be drinking in a way that could be harmful, plus provision of an advice leaflet, will be given by the learning mentor.

Intervention 1 In addition to PSHE, the young people who are eligible (risky drinkers) and consent to participation will be given feedback that they may be drinking in a way that could be harmful and provided with an advice leaflet. They will then take part in a 30-minute personalised interactive worksheet-based session. This will be delivered by the learning mentor (at school).

Young people will be followed up at 12 months. The hypothesis for the definitive trial is that ASBI is more effective and cost-effective at reducing hazardous drinking in young people (aged 14–15 years) than a control condition of usual advice, as well as feedback and a leaflet.

Conclusions

It is feasible and acceptable to carry out a trial of ASBI in the school setting with young people aged 14–15 years, with learning mentors delivering the intervention. Learning mentors, parents and young people questioned the utility of an intervention that they believed was not engaging the 'right' people. Although parents who did engage in intervention 2 found the intervention to be acceptable, most young people and their parents who were offered did not express a desire to take part in this intervention or benefit from doing so, and some young people who were interviewed told us that they did not want to have their parents involved. Future work should include a definitive study which does not include a parental arm.

Trial registration

The trial is registered as ISRCTN07073105.

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