

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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**National Institute for
Health Research**

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Abstract

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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Background: Approximately 33% of 15- to 16-year-olds in England report alcohol intoxication in the past month. This present work builds on the evidence base by focusing on Alcohol Screening and Brief Intervention (ASBI) to reduce hazardous drinking in younger adolescents.

Objectives: To explore the feasibility and acceptability of a future definitive cluster randomised controlled trial (cRCT) of ASBI in a school setting to staff, young people and parents; to explore the fidelity of the interventions as delivered by school learning mentors; 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; and to pilot the collection of cost and resource-use data to inform the cost-effectiveness/utility analysis in a definitive trial.

Setting: Seven schools across one geographical area in North East England.

Methods: Feasibility of trial processes, recruitment and retention and a qualitative evaluation examined facilitators and barriers to the use of ASBI approaches in the school setting in this age group. A three-arm pilot cRCT (with randomisation at the school level) with qualitative evaluation to assess the feasibility of a future definitive cRCT of the effectiveness and cost-effectiveness of ASBI in a school setting, with an integrated qualitative component. The trial ran in parallel with a repeated cross-sectional survey, which facilitated screening for the trial.

Participants: Year 10 school pupils (aged 14–15 years).

Interventions: Young people who screened positive on a single alcohol screening question, and consented to take part, were randomised to one of three groups: (1) feedback that their drinking habits may be risky and provision of an advice leaflet (control condition, $n =$ two schools); (2) feedback as for the control condition plus a 30-minute brief interactive session, which combined structured advice and motivational interviewing techniques, delivered by the school learning mentor (intervention 1, $n =$ two schools); or (3) feedback as for the control condition plus a 30-minute brief interactive session as for intervention 1 plus a 60-minute session involving family members delivered by the school learning mentor (intervention 2, $n =$ three schools). Young people were followed up at 12 months.

Main outcome measures: Feasibility and acceptability.

Randomisation: Randomisation was carried out at the school level. Randomisation achieved balance on two school-level variables (numbers of pupils in school year and proportion receiving free school meals).

Blinding: School staff, young people and researchers were not blind to the intervention allocated.

Results: A total of 229 young people were eligible for the trial; 182 (79.5%) were randomised (control, $n = 53$; intervention 1, $n = 54$; intervention 2, $n = 75$). Of the 75 randomised to intervention 2, 67 received intervention 1 (89%). Eight received both intervention 1 and intervention 2 (11%). In total, 160 out of 182 were successfully followed up at 12 months (88%). Interviews were carried out with six school lead liaisons, 13 learning mentors, 27 young people and seven parents ($n = 53$). Analysis shows that the school setting is a feasible and acceptable place to carry out ASBI, with learning mentors seen as suitable people to do this. Intervention 2 was not seen as feasible or acceptable by school staff, parents or young people.

Outcomes/conclusions: It is feasible and acceptable to carry out a trial of the effectiveness and cost-effectiveness of single-session ASBI with young people in the school setting, with learning mentors delivering the intervention. Future work should include a definitive study that does not include a parental arm.

Trial registration: Current Controlled Trials ISRCTN07073105.

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Glossary

Alcohol Screening and Brief Intervention Alcohol Screening and Brief Intervention is a secondary preventative activity, aimed at individuals whose consumption level or pattern is likely to be harmful to their health or well-being. They generally consist of screening (to identify relevant recipients) followed by structured advice or counselling of short duration, which is aimed at reducing alcohol consumption or decreasing the number or severity of problems associated with drinking.

Control The control condition consisted of feedback that the young person was drinking in a way that may be harmful and provision of an advice leaflet delivered by the school learning mentor.

Intervention 1 The intervention 1 condition consisted of feedback that the young person was drinking in a way that may be harmful and provision of an advice leaflet – a 30-minute brief interactive session that combines structured advice and motivational interviewing techniques delivered by the school learning mentor.

Intervention 2 The intervention 2 condition consisted of feedback that the young person was drinking in a way that may be harmful and provision of an advice leaflet – a 30-minute brief interactive session that combines structured advice and motivational interviewing techniques, delivered by the school learning mentor, plus a 60-minute session involving family members, also delivered by the school learning mentor.

Learning mentor Learning mentors are specifically trained to provide a service complementary to that of teachers and other school staff, addressing the needs of children who require assistance in overcoming barriers to learning in order to achieve their full potential. Learning mentors support, motivate and challenge pupils who are underachieving. They help pupils overcome barriers to learning caused by social, emotional and behavioural problems.

Participants to the trial Participants to the trial were young people who screened positively on a single alcohol screening question, left their name on the questionnaire and gave consent.

List of abbreviations

A-SAQ	Adolescent Single Alcohol Question	EQ-5D-Y	European Quality of Life-5 Dimensions (Youth version)
AC	assessed control		
ADAD	Alcohol and Drug Abuse Division	FRAMES	Feedback, Responsibility, Advice, Menu, Empathy and Self-efficacy
ASBI	Alcohol Screening and Brief Intervention	GAIN	Global Appraisal of Individual Needs
AUD	alcohol use disorder	GAIN-I	Global Appraisal of Individual Needs – Initial version
AUDIT	Alcohol Use Disorders Identification Test	GP	general practitioner
AUDIT-C	AUDIT-Consumption (first three questions of full AUDIT)	IMI	Individual Motivational Interviewing
BAC	blood alcohol concentration	M-SASQ	Modified-Single Alcohol Screening Question
BASICS	Brief Alcohol Screening and Intervention for College Students	MAP	Maudsley Addiction Profile
BDI-II	Beck Depression Inventory version II	MDMA	3,4-methylenedioxy- <i>N</i> -methylamphetamine
BECCI	Behaviour Change Counselling Index	MI	motivational interviewing
BI	brief intervention	MRC	Medical Research Council
BLC	Brief Lifestyle Counselling	NIHR	National Institute for Health Research
CBT	cognitive-behavioural therapy	NYSDS	National Youth Survey Delinquency Scale
CDISC	Clinical Diagnostic Interview Schedule for Children	OR	odds ratio
CI	confidence interval	PANSS	Positive and Negative Symptom Scale
CISS	Coping Inventory for Stressful Situations	PMG	Programme Management Group
CMO	Chief Medical Officer	POSIT	Problem Orientated Screening Instrument for Teenagers
CONSORT	Consolidated Standards of Reporting Trials	PPI	patient and public involvement
cRCT	cluster randomised controlled trial	PSHE	Personal, Social, Health and Economic Education
DAST	Drug Abuse Screening Test	QALY	quality-adjusted life-year
DSM-III-R	<i>Diagnostic Statistical Manual</i> version III, Revised	RAPI	Rutgers Alcohol Problems Index
DSM-IV	<i>Diagnostic Statistical Manual</i> version IV	RCT	randomised controlled trial
EQ-5D	European Quality of Life-5 Dimensions	S-SUQ	Short Service Use Questionnaire
		SD	standard deviation

LIST OF ABBREVIATIONS

SES	socioeconomic status	TP2	time point 2
SHAHRP	School Health and Alcohol Harm Reduction Project	TP3	time point 3
SRD	Self-Report Delinquency Scale	TSG	Trial Steering Group
SUD	substance use disorder	UCC	usual continuing care
SUS	'Stop Using Stuff'	WEMWBS	Warwick–Edinburgh Mental Well-being Scale
TAU	treatment as usual	WHO	World Health Organization
TLFB	Timeline Followback	YSR	youth self-report
TP1	time point 1		

Plain English summary

Approximately 33% of 15- to 16-year-olds in England report alcohol intoxication in the past month. This study assessed the feasibility of the effectiveness and cost-effectiveness of a study of alcohol screening and brief alcohol intervention (ASBI) in a school setting to reduce risky drinking in adolescents aged 14–15 years in seven high schools in North East England. A survey using questionnaires to measure risky drinking was administered to all young people whose parents had consented to them taking part. Young people were randomly allocated to one of three groups. Each group received an intervention administered by trained school staff: (1) no intervention (control) – they received feedback that they may be drinking in a way that may be harmful to them and were given an alcohol information leaflet; (2) intervention 1 – a 30-minute one-to-one brief interactive advice session, as well as an alcohol information leaflet; or (3) intervention 2 – young people allocated to intervention 2 received the same input as intervention 1 plus the offer of a 1-hour session with parental/family involvement. The study included in-depth interviews with school staff, parents and young people to explore their views on how best to deliver the intervention. Results showed that it is feasible and acceptable to carry out ASBI in a school setting. A total of 182 young people were recruited to the study; however, only 8 of the 75 people allocated to the family involvement group had a family meeting. Results show that a definitive study should focus on working with young people rather than involving parents.

Scientific summary

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.

Funding

Funding for this study was provided by the Public Health Research programme of the National Institute for Health Research.

Chapter 1 Structure of the report

This study assessed the feasibility of a cluster randomised controlled trial (cRCT) of Alcohol Screening and Brief Intervention (ASBI) (in a school setting) to reduce hazardous drinking in adolescents. This was achieved by way of 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 small local authority area of North East England. 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). The study included an integrated qualitative process evaluation (*Figure 1*) with key stakeholders. The three arms were control, intervention 1 and intervention 2. Young people allocated to the control arm received feedback and an alcohol information leaflet only. Young people allocated to intervention 1 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. Young people allocated to intervention 2 received the same input as intervention 1 plus a subsequent session, facilitated by trained school staff, with parental/family involvement.

Research questions

The Medical Research Council (MRC) has presented a framework for the evaluation of complex interventions.¹ This work represents the development and piloting phases of the framework. Conducting a full-scale cRCT and economic evaluation of ASBI compared with 'standard care' in this population is likely to need many schools and to be resource intensive. As there are uncertainties regarding rates of eligibility, consent, participation in the intervention and retention for follow-up and regarding the feasibility and acceptability of the intervention for a range of stakeholders (teachers, learning mentors, young people and parents) this feasibility study was essential to inform the design and conduct of a larger scale definitive study.

The study sought to answer the following research questions: 'Is it feasible to deliver ASBI in schools in England?' and 'What are the likely eligibility, consent, participation and retention rates of young people in a UK-relevant trial of ASBI compared with standard practice?'. Answers to these research questions will inform the development of a definitive multicentre cRCT to evaluate the effectiveness and cost-effectiveness of ASBI in reducing hazardous drinking in adolescents. Our hypothesis for the definitive cRCT will be that ASBI is more effective and cost-effective at reducing hazardous drinking in adolescents than a control condition of usual advice in high/comprehensive schools, as well as feedback on their drinking and an information leaflet.

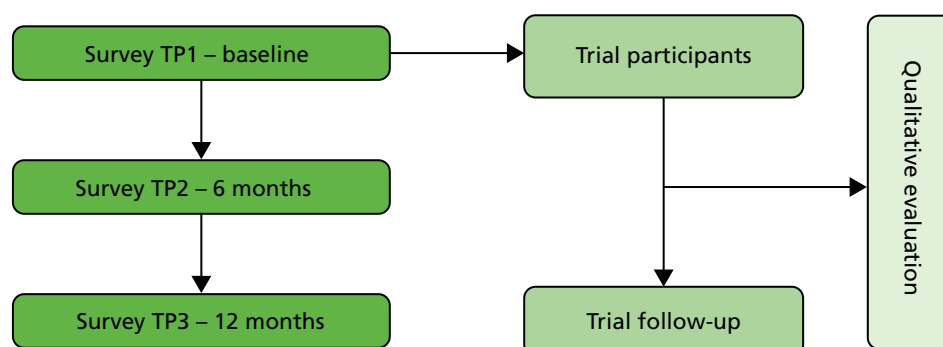


FIGURE 1 Data time points for the study. TP, time point.

Research objectives

1. To conduct a three-arm pilot feasibility 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 ASBI, 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 ASBI compared with standard advice to reduce alcohol consumption.

Chapters of the report

The report is structured as a series of eight chapters detailing the design, management and outcomes of the pilot feasibility study. The report begins by providing the background to the research and outlines key literature informing the design and conduct of the study (see *Chapter 2*). Following this, a chapter is dedicated to each core component of the study. *Chapter 3* explores the design of intervention materials as well as the training and support provided to school staff in the delivery of the project. *Chapter 4* reports the design, methods and results of the repeated cross-sectional survey. *Chapter 5* provides the design, methods and results of the external pilot trial. *Chapter 6* details the design, methods and results of the integrated qualitative process evaluation. *Chapter 7* details the design, methods and results of the health-economic evaluation of the study. Finally, *Chapter 8* provides a synthesis of the main findings from the pilot feasibility study, together with an assessment of whether the study met its aims and objectives, before detailing any recommendations for a future definitive cRCT.

Research ethics

The research study was granted ethical approval in November 2011 by Newcastle University, which acted as a sponsor for the research (reference 0508), and the trial is registered with the ISRCTN register as ISRCTN07073105. Approval was also granted by the local education authority in the study catchment area. Ethical approval was extended to accommodate a change in study protocol in October 2012, which related to measures completed at the 12-month follow-up of trial participants.

Changes to the original study protocol

The study protocol was published in 2012.²

1. The published protocol indicates 6- and 12-month follow-ups for the trial group; however, it is not clear on the protocol that the full year group was followed up at 6 months and 12 months, as no identifiable data were taken at the year group level or the trial participant level at 6 months, therefore we have identifiable data for only the trial group at baseline and 12-month follow-up. The reason for this was that having a one-on-one interaction with the learning mentor could have acted as a 'top-up' to the intervention. We do not intend to include a 6-month follow-up in the proposed definitive study.
2. Objective 5 of the study – 'to pilot the collection of cost and resource-use data to inform the cost-effectiveness/utility analysis in a definitive trial' – was not included in the original study protocol.

3. The original protocol reported the control group as Personal, Social, Health and Economic Education (PSHE) only; however, the control condition was PSHE and also included the young person receiving feedback that he/she was drinking in a way that may be harmful and being provided with an advice leaflet. The reason that we added feedback and the leaflet (and therefore a change to the protocol) was that the research team and the University Ethics Committee believed that this was the minimally acceptable thing we could ethically do should a young person be identified as a risky drinker.

Research management

The Programme Management Group (PMG) was responsible for ensuring the appropriate, effective and timely implementation of the project. The PMG met once per month (more or less frequently dependent on the needs of the project) and comprised the Chief Investigator, Project Manager, co-applicants, named collaborators and researchers working on the project. Professor Eilish Gilvarry chaired this group. A Trial Steering Group (TSG) was also appointed to provide an independent assessment of the data analysis and to help determine if a future definitive trial is merited. This group met biannually and their remit was the progress of the study against projected rates of recruitment and retention, adherence to the protocol, participant safety and the consideration of new information of relevance to the research question. Professor Mark Bellis chaired this group. Written terms of reference were agreed and used by the PMG and TSG (see *Appendix 1*).

Research governance

The project complied with the requirements of the Data Protection Act 1998 and the Freedom of Information Act 2000, and other UK and European legislation relevant to the conduct of clinical research. The project was managed and conducted in accordance with the MRC's guidelines on good clinical practice in clinical trials (www.mrc.ac.uk), which includes compliance with national and international regulations on the ethical involvement of patients in clinical research (including the Declaration of Helsinki, sixth revision 2008). All data were held in a secure environment with participants' information identified by a unique participant identification number. Master registers containing the link between participant identifiable information and participant identification numbers were stored in a secure area that was separate from the majority of data. All staff working on the project were employed by academic organisations and subject to the terms and conditions of service and contracts of employment of the employing organisations. Where relevant, staff were trained in good clinical practice and all staff worked to written codes of confidentiality. The project used standardised research and clinical protocols, and adherence to the protocols was monitored by the PMG and TSC.

Patient and public involvement

Patient and public involvement (PPI) was sought at different time points and at multiple levels, and is reflected upon throughout this report.

Patient and public involvement representatives included local authority employees, parents, young people and members of staff at participating school sites. Their contribution to the development, management and delivery of this research included input into the design and conduct of the feasibility study (the local authority lead for education was a co-applicant for this research) and piloting of study documentation and intervention materials (parents and young people) to ensure readability and understanding (see *Chapter 3*). Participating schools were also heavily involved in the conduct of the feasibility study (trial and survey) and were regarded as key stakeholders (see *Chapters 4 and 6*). Finally, *Chapter 8* includes modifications recommended for a definitive trial, which include input from PPI representatives.

Chapter 2 Background to the research

Key points for Chapter 2

- Adolescents in England are among the heaviest drinkers in Europe, with consumption highest in the north-east.
- Young people are more vulnerable than adults to the adverse effects of alcohol owing to a range of physical and psychosocial factors that often interact.
- Literature shows that the ASBI for young people has been successful for selected individuals in certain settings.
- There is currently insufficient evidence to be confident about the use of ASBI to reduce risky drinking and alcohol-related harm in younger adolescents in a school setting.
- Despite well-documented parental influences over adolescent alcohol use, the evidence for interventions to reduce young people's drinking that include family members is equivocal.

Prevalence

Adolescents in England are among the heaviest drinkers in Europe.³ The percentage of young people who have ever had an alcoholic drink in England increases with age from 12% of those aged 11 years to 74% of those aged 15 years,⁴ and the prevalence of drinking in the last week rises from 1% of those aged 11 years to 25% of those aged 15 years.⁴ Although the proportion of young people in England aged between 11 and 15 years who report that they have ever drunk alcohol decreased from 54% to 43% between 2007 and 2012, the mean amount of alcohol consumed by this age group has fluctuated between 10.4 units per week in 2011 and 14.6 units per week in 2008, with an increase to 12.5 units per week in 2012. There are, however, age-related differences in patterns of consumption. The amount consumed among those aged 14 years has increased from 13.2 units per week in 2007 to 16.15 units in 2012, whereas for 15-year-olds the mean amount has decreased slightly from 14.2 units per week in 2007 to 12.3 units in 2012.⁴ This clearly shows that drinking increases throughout adolescence, but recent data show that this is not immutable with changes in trends between years and age.

In particular, the north-east has been shown to have the highest rates of alcohol misuse by young people in England, with 51% of 11- to 15-year-olds reporting having ever drunk alcohol.⁴ This compares with 48% in the south-east, 46% in the north-west and 31% in London.⁴ Further, the mean alcohol consumption in the previous week for young people in England in 2011 was highest in the north-east and north-west (15.7 units per week) compared with the south-east (11.0 units) and London (9.4 units).⁴ Therefore, the north-east is a key place to study the issue of alcohol risk reduction in young people.

Consequences of drinking

The impact of alcohol on the development and behaviour of young people has been well researched in early,⁵ middle⁶ and late adolescence.⁷ It is now well known that young people are much more vulnerable than adults to the adverse effects of alcohol due to a range of physical and psychosocial factors that often interact.⁸ These adverse effects include physiological factors resulting from a typically lower body mass and less efficient metabolism of alcohol;^{5,6} neurological factors due to changes that occur in the developing adolescent brain after alcohol exposure;^{6,9-11} cognitive factors due to psychoactive effects of alcohol that impair judgement and increase the likelihood of accidents and trauma;¹² and social factors that arise from a typically high-intensity drinking pattern that leads to intoxication and risk-taking behaviour.^{13,14} The social factors are compounded by the fact that young people have less experience of dealing with the effects of

alcohol than adults¹⁵ and they have fewer financial resources to help buffer the social and environmental risks that result from drinking alcohol.⁷

Evidence suggests that hazardous drinking among young people occurs commonly in the context of other forms of 'disinhibitory behaviour', such as aggression and risk-taking.¹⁶ Although these behaviours are well known to be linked,¹⁶ it is not clear if drinking leads to these behavioural problems or if they all arise due to a common linked trait.¹⁷ A significant positive association between alcohol dose and aggression for both genders has been found.¹⁸ As a result of the above risk factors, the list of negative consequences that result from drinking in young people is extensive and includes physical, psychological and social problems in both the shorter and the longer term. Immediate problems result from accidents and trauma, physical and sexual assault (including rape in young people), criminal behaviour (including driving while intoxicated and riding as a passenger with an intoxicated driver) and early onset of sexual intercourse and sexual risk-taking.^{8,14,19} In relation to education, alcohol use can have a negative effect on school performance²⁰ and those who have drunk are also more likely to have truanted from school.⁴ Longer-term problems include the development or exacerbation of mental health problems,²¹ self-harm and/or suicidal behaviour.²² Moreover, individuals who begin drinking in early life have a significantly increased risk of developing alcohol use disorders, including dependence, later in life.^{23,24} Owing to this extensive array of damage, the prevention of excessive drinking in young people is a global public health priority.²⁵ In 2009, the Chief Medical Officer for England provided recommendations on alcohol consumption in young people,²⁶ based on an evidence review of the risks and harms of alcohol to young people.⁸ The recommendations state 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.²⁶

Young people's views on their own health

It is important to note that young people often feel that they want to be empowered to be part of any decision-making in relation to their own health and feel that they have choices (C Sands, Newcastle University, 2013, unpublished data). For young people, confidentiality is a key issue, particularly within the school setting. However, to young people it is really important that they are familiar with the staff working with them, and therefore these issues should be taken into consideration when undertaking research with young people.

Primary and secondary prevention interventions for risky drinking

There is a large volume of evidence on primary prevention in the school setting,^{27–32} which is directed at all young people, whether they drink alcohol or not, with the aim of delaying the age at which drinking begins, and which uses general health education to prevent underage drinking. This body of work has shown mixed results and been reported to be methodologically weak,³³ with only a relatively small number of programmes reporting positive outcomes.³⁰ One programme that has shown effectiveness is the School Health and Alcohol Harm Reduction Project (SHAHRP) project, a curriculum programme delivered across two consecutive school years in Ireland with 2349 pupils (mean age of 13.84 years at baseline and 16.48 years at final follow-up at 32 months). The programme had an explicit harm-reduction goal that explores knowledge, attitudes, alcohol consumption, and context of use and harms associated with a person's own, or other people's, use of alcohol. This showed significant improvements among young people in the intervention group in relation to alcohol knowledge and significant reductions in alcohol consumption.³⁴ Furthermore, research from the USA found that targeting young people and parents simultaneously but separately was effective in postponing the onset of heavy drinking among adolescents.^{35,36} However, the results are equivocal, with some studies showing effectiveness and others not, and questions remain about the applicability to the UK setting.²⁷ As has been shown, there is limited

evidence to support primary prevention programmes to reduce alcohol consumption in young people. 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 interventions will have more salience for the individuals receiving them.

Various screening measures have been used with young people to identify those who are at risk from their drinking including using measures of total alcohol consumption, levels of binge drinking and alcohol-related injury levels.³⁷ Research suggests standardised alcohol screening tools, such as the Alcohol Use Disorders Identification Test (AUDIT)³⁸ are a highly sensitive and specific means of identifying current hazardous use of alcohol in adult populations, including college students.^{39–41} Among adult drinkers, the AUDIT detects approximately 92% of genuinely excessive drinkers (sensitivity) and excludes approximately 94% of false cases (specificity),^{42,43} for which a cut-off score of ≥ 8 (out of a possible score of 40) is used to detect hazardous use of alcohol and alcohol-related problems. Broken down further, respondents can be categorised as 'abstainers' (0); 'lower risk' drinkers (1–7); at 'increasing risk' (8–15); at 'higher risk' (16–19); or 'probably dependent' (≥ 20).

There is some evidence from emergency department settings in the USA to suggest that the AUDIT is an appropriate means of detecting hazardous use of alcohol and alcohol-related problems among adolescents.^{44–46} However, evidence remains equivocal whether it is either practical or appropriate for use with adolescents in other settings, including primary care and education. At 10 items, the length and wording of the full AUDIT may make it impractical for use with adolescents.^{42,47} Evidence is especially equivocal as to the AUDIT tool's ability to detect hazardous level drinking (the AUDIT positive score) among this age group or whether the concepts of hazardous or harmful drinking in adults are similarly meaningful in adolescents. Several studies have used AUDIT positive cut-off scores of '8', designed for use with adults, to screen for alcohol use disorders among adolescents.^{47,48} In comparison, other evidence supports using lower cut-off points, which generally fall between '2' and '4',^{43,49,50} when using the AUDIT in adolescent populations. For example, Chung *et al.*⁴⁴ recommend using a cut-off score of '4' with young people aged 13–19 years (sensitivity 0.94; specificity 0.80) and Knight *et al.*⁵⁰ suggest that a score of '2' is optimum for the identification of alcohol problems and disorders among those aged 14–18 years (sensitivity 0.88; specificity 0.81). Santis *et al.*⁴⁹ suggest different scores according to the level of alcohol consumption, with cut-off points of '3' for hazardous, harmful and dependent alcohol use (sensitivity: 96%; specificity: 63.3%), '5' (sensitivity: 75%; specificity: 64.5%) and '7' (sensitivity 64%; specificity 75%), respectively.

Others suggest using a shortened version of the AUDIT tool, such as AUDIT-C (AUDIT-Consumption), which is scaled 0–12, and for which a score of ≥ 5 (among adults) is used to indicate increasing or higher risk drinking.^{40,51} No specific score for young people has yet been recommended. It has also been shown that a single question screen based on drinking frequency can adequately identify youths with alcohol-related problems.^{52,53} Bailey *et al.*⁵³ used the frequency of binge drinking (question three of the AUDIT tool – six or more drinks in one drinking session) to identify risky drinking in young people.⁵³ Thus, there is no clear consensus on which screening tool should be used, the validity of lower AUDIT or AUDIT-C cut-off points for use with adolescent populations or as to what this score should be, and whether the AUDIT or AUDIT-C or another measure should be the screening measure of choice. It could therefore be argued that in a school setting a shorter screening tool could be useful, and quick, to administer.

In terms of interventions for dealing with people who are drinking at harmful or hazardous levels, ASBI is a secondary preventative activity, aimed at individuals whose consumption level or pattern is likely to be harmful to their health or well-being.⁵⁴ They generally consist of screening (to identify relevant recipients) followed by structured advice or counselling of short duration, which is aimed at reducing alcohol consumption or decreasing the number or severity of problems associated with drinking.⁵⁵ They are based on social cognitive theory (from health psychology), which is drawn from the concept of social learning.⁵⁶ Here, behaviour is regarded to be the result of an interaction between individual, behavioural and environmental factors. It is assumed that each individual has cognitive (thinking) and

affective (feeling) attributes that affect not only how they behave, but also how their behaviour is influenced and/or reinforced by aspects of the external world. Thus ASBIs 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).

A key feature of ASBI is that it is designed to be delivered by generalist practitioners (not addiction specialists) and targeted at individuals who are generally not experiencing severe problems (such as alcohol dependence) and who may not even be aware that they are experiencing alcohol-related risk or harm. Thus the goal is usually reduced alcohol consumption or a decrease in alcohol-related problems.⁵⁷ There is variation in the duration and frequency of ASBI⁵⁸ but there are two broad types: simple structured advice – based on the FRAMES (Feedback, Responsibility, Advice, Menu, Empathy and Self-efficacy)⁵⁹ – and behaviour change counselling – based on MI. This is a person-centred approach that aims to resolve conflicts regarding the pros and cons of behaviour change and thus enhance motivation. MI is characterised by empathy and an avoidance of direct confrontation. Elicited statements associated with positive behaviour change are encouraged so as to support self-efficacy and a commitment to take action. Since the time available for delivering BI may not allow for MI in its full form,⁵⁸ its ethos and techniques have been⁵⁹ distilled into a more directive format called Behaviour Change Counselling.⁶⁰

There is a large amount of high-quality evidence to support the effectiveness of ASBI with adults who have an alcohol use disorder.⁵⁸ Most of the evidence for ASBI demonstrates effectiveness for non-treatment-seeking adults in primary health care.^{58,61–68} Furthermore, meta-analyses have consistently reported that students aged ≥ 18 years who received ASBI subsequently reduced their drinking behaviour compared with control group participants who typically received assessment only.^{69,70} The key elements of the ASBI were personalised feedback on alcohol consumption, typically with a normative component⁷⁰ and/or MI approaches. Such interventions typically achieved small to medium effect sizes⁷¹ across multiple measures of alcohol consumption, including quantity, frequency and intensity of drinking. The effects of BIs on drinking behaviour often peaked in the shorter term (generally 6 months) then diminished over time.⁶⁹ However, reductions in alcohol-related problems often took longer to emerge but were found in longer-term follow-up (12–18 months). Hence it is important to have BI outcomes measuring both consumption and alcohol-related problems and to follow-up participants at shorter- and longer-term time points.

Numerous systematic reviews have been published on ASBI in younger adolescents in recent years^{37,72–79} (details given in *Appendix 2*). Jackson *et al.*'s review³⁷ of ASBI for young people in health settings identified eight controlled trials^{53,80–85} for young people. The work was part of a larger review of ASBI in adults and young people. The trials were published between 1999 and 2009 and the majority (seven)^{80–86} were carried out in the USA. Study population sizes ranged from 34 to 655 young people and included young people aged between 12 and 24 years with two of the included studies being for those aged ≥ 18 years only. Five of the trials tested a brief MI, which lasted between 20–45 minutes,^{81,83–86} whereas one tested an audio programme;⁸⁰ another involved a more intense programme of MI which included four sessions⁵³ and one comprised an interactive laptop computer-based intervention.⁸² The length of follow-up varied between 2 and 12 months. Four of the studies^{53,83–85} found statistically significant benefits as a result of the intervention. However, one⁸⁰ of the studies found negative consequences following intervention, with an increase in heavy alcohol use among the intervention group. The authors offer two possible explanations for this. First, adolescents in the control group, unlike adolescents in the intervention groups, reported less bingeing after baseline, suggesting self-report bias in the direction anticipated if the control adolescents were trying to please the researchers. Second, the authors argue that the apparent increase in self-reported alcohol use in the intervention groups relative to the control groups was the result of an educational intervention influence leading adolescents to be more forthright.⁸⁰ Wachtel and Staniford⁷⁷ also reviewed the literature in relation to alcohol misuse and binge drinking in adolescents in the clinical setting (hospital-based emergency departments, college health centres and adolescent healthcare clinics).⁷⁷ The review included 14 studies,^{53,80,82–85,87–94} 12 of which were from the USA.^{53,80,82–85,87–91,93} Nine of the included studies^{83,84,87–93} related to young people aged ≥ 18 years and included a heterogeneous range of interventions from very brief MI to four group sessions of 30–40 minutes, which meant that generalisability

could not be ascertained. A review of the literature by Yuma-Guerrero *et al.*⁷⁸ around BI in emergency departments in the USA for young people identified seven randomised controlled trials (RCTs).^{82–85,95–97} The primary studies included young people aged 12–20 years. Four^{82–84,98} of the included studies demonstrated a significant intervention effect; however, none reduced both alcohol consumption and alcohol-related consequences.

Mitchell *et al.*'s systematic review⁷⁵ identified 15 studies^{81,82,85,86,95–105} of alcohol and drug interventions delivered to adolescents in primary care (one study⁸¹), emergency departments (seven studies^{82,85,95–98,103}), schools (five studies^{99,101,104–106}) and other settings (one study with homeless young people⁸⁶ and one in the community¹⁰⁰) with young people aged 12–21 years. The authors identify the need for screening instruments to be brief to administer and quick and easy to score and interpret.⁷⁵ Because of the heterogeneous populations (ages 12–22 years), inclusion criteria (adolescents who use alcohol and drugs as well as those who reported being in a car with an intoxicated driver but who themselves had not used alcohol or drugs) and differences in outcome measures, the data did not allow for meta-analysis, although some individual studies did show reductions in alcohol consumption at follow-up. The review identified two studies^{101,102,106} (three articles) carried out in further education colleges in the UK, with older young people aged between 16 and 20 years, in which no differences were found between groups at 12-month follow-up.

Three systematic reviews included meta-analyses of ASBI for young people.^{73,74,76} Tripodi *et al.*⁷⁶ carried out a meta-analytic review on interventions for alcohol abuse in a range of settings. Sixteen primary studies were included with young people aged 12–19 years.^{81,105,107–120} The studies included various interventions including BI, cognitive-behavioural therapy (CBT) and multidimensional family therapy. The main outcome measures included abstinence and quantity of alcohol use measured between 1 and 12 months post intervention. Pooled effects of standardised mean differences indicate that interventions significantly reduce alcohol consumption [Hedges' $g = -0.61$; 95% confidence interval (CI) -0.83 to -0.40]. Stratified analyses revealed larger effects for individual treatment (Hedges' $g = -0.75$; 95% CI -1.05 to -0.40) compared with family-based treatments (Hedges' $g = -0.46$; 95% CI -0.66 to -0.26).⁷⁶

Jensen *et al.*'s review⁷⁴ of the effectiveness of MI for substance-use interventions for adolescents included 21 primary studies, of which 12 had alcohol-related outcomes.^{53,81,85,86,99–102,108,121–123} These studies were from a variety of different settings: educational,^{99,101,102,123} community^{53,86,100,108} and health.^{81,85,121,122} No information was given on the nature of the interventions; however, the number of sessions ranged from one to four. The age range included in the studies was 12–23 years. Included studies that addressed alcohol and other drug use yielded a small, but significant, post-treatment effect size in reduction of substance use [mean d (standard mean difference) = 0.146 (95% CI 0.059 to 0.233), $n = 16$].

Carney *et al.*'s meta-analysis⁷³ aimed to identify and evaluate early interventions that target adolescent substance use (alcohol and illicit drugs) as a primary outcome, and criminal or delinquent behaviours as a secondary outcome. They identified nine studies^{53,81,85,86,97,99,109,124,125} in emergency departments, juvenile correctional facilities, alternative high schools and a homeless drop-in centre – eight from the USA^{81,85,86,97,99,109,124,125} and one from Australia.⁵³ Study sizes ranged from 18 to 472. The age range was 15–17 years. Results showed that single sessions of BIs significantly reduced the frequency of alcohol use among young people ($I^2 = 0\%$; $z = 2.13$; overall effect, $p = 0.03$).⁷³

Conrod *et al.*^{126–128} have carried out a number of trials in London of group-based personality-targeted prevention for young people aged 13–14 years who are risky drinkers or drug users. The interventions consisted of two 90-minute group sessions that incorporated components of motivational enhancement therapy and CBT. The intervention was unique in that it targeted personality traits rather than problems. In fact, alcohol and drug use were a minor focus of the intervention. Young people have been followed up every 6 months for 2 years and long-term effects (at 2 years) have been found for problem drinking (measured using the Rutgers Alcohol Problems Index (RAPI) tool) ($p = 0.02$) and binge-drinking rates ($p = 0.03$). Finally, a study of US accident and emergency attendees^{97,129} who received ASBI showed reductions in aggression, as well as reductions in alcohol misuse following a brief alcohol intervention.

It has been shown that the family is a source of both risk and protective factors for adolescent alcohol use.⁸ Parents in particular have been found to have a significant effect upon alcohol initiation and patterns of use.¹³⁰ Such parental factors include parental modelling,^{131–133} supervision and discipline,⁸ quality of parent–child relationship and communication among others.¹³⁴ It is therefore important to identify whether parents can play a role in helping to reduce their children’s drinking.

Parents

The majority of parents are aware that their children are drinking.¹³⁵ Parenting ‘style’ and ‘good’ family relationships have been demonstrated to have a positive effect on young people’s drinking behaviour regardless of family structure or whether parents consume alcohol.^{8,134,136} Excessively authoritarian and permissive parenting styles are both associated with earlier onset of alcohol use or higher levels of drinking behaviour,^{137,138} and Foxcroft and Lowe¹³⁹ identify a possible curvilinear relationship between control and adolescent drinking, where significantly stricter or lax parenting styles appear to increase the frequency of alcohol misuse.

Parents can also be a primary source of the supply of alcohol to young people.^{140,141} This may be through the provision of money, by having alcohol available or by purchasing alcohol for young people directly. Easy availability of alcohol is associated with increased adolescent alcohol consumption¹⁴² and Elliott *et al.*¹⁴¹ found that 65% of drinkers (aged 11–17 years) accessed alcohol via their parents. Further, it is implicitly assumed that if parents purchase alcohol for their children directly, the amount of alcohol consumed can be strictly monitored. In other words, that providing young people with alcohol will stop them from accessing it elsewhere, thus reducing the risk of alcohol-related harm. Again, the evidence for this is equivocal. On the one hand, Bellis *et al.*¹⁴³ found that (in contrast with other ways of obtaining alcohol) young people (aged 15–16 years) whose parents bought alcohol for them were less likely to drink in a public setting, ‘binge’ drink, drink heavily or drink frequently. On the other hand, receiving alcohol from a parent or getting it from home has been demonstrated to be the strongest predictor of increased alcohol use over time.¹⁴⁴ However, Gilligan *et al.*¹⁴⁵ found that negative outcomes from parental provision of alcohol are dependent on the context of supply. In other words, if parents supplied young people with alcohol, this did not increase the odds of risky drinking (although it also did not have the protective effect that motivated the behaviour). However, if alcohol was supplied for consumption without parental supervision then the odds of risky drinking were four times higher.

Given the well-documented parental influences over adolescent alcohol use, interventions that aim to involve parents who 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.¹³⁴

Alcohol Screening and Brief Interventions that include parents

Mixed effects have been found for ASBI for reducing young people’s drinking that include family members.^{33,54,146,147}

A RCT examining the effectiveness of 45–60 minutes of individual motivational interviewing (IMI) compared with IMI and a family check-up session found that both interventions resulted in significant reduction of drinking outcomes at 3-, 6- and 12-month follow-ups. The family check-up consisted of a 1-hour meeting, at which the parent(s) and the young person discussed family beliefs regarding alcohol and other drug use. Results show there was only one significant between-group difference on the number of high-volume drinking days at 3- and 6-month follow-up, with family check-up reporting lower alcohol prevalence compared with IMI. This effect had diminished at 12-month follow-up.¹⁰³

A RCT with three arms: (1) two 60-minute individual sessions of BI (young person and interventionist only); (2) two 60-minute individual sessions of BI (young person and interventionist only) and a BI session with the parent(s) [parent(s) and interventionist only]; and (3) control arm of assessment only found that both intervention groups showed significantly better drinking outcomes than the control arm for number of alcohol days and number of binge days with a small sample ($n = 78$). The intervention arm that included parental involvement reported significantly fewer alcohol days at 6-month follow-up than the intervention group without parental involvement but no difference in number of binge days.¹⁰⁵ This study was repeated with a large sample ($n = 315$) and, again, both intervention arms were found to be superior to the control condition. Significant between-group differences were reported by this trial in favour of the arm with parental involvement for drug outcomes but not alcohol. Indeed, the intervention arm without parental involvement reported significantly greater alcohol abstinence in the previous 90 days than the arm with parental involvement.¹²⁵

Mixed results have been found for intensive BIs for drug and alcohol using adolescents, with parental involvement (see *Appendix 2*).^{112,115,117,148,149} However, significant variation exists between experimental conditions examined with regards to both the intensity and the frequency of the intervention (ranging from a single 1-hour family check-up to 64 hours of family and individual CBT), as well as the theoretical basis of the therapeutic approach. Moreover, the heterogeneity of the adolescent samples, which included dually diagnosed adolescents, risky drinkers, drug and alcohol users, runaways and gang-affiliated young people, made it difficult to compare the findings of the trials. Therefore, the evidence is equivocal.

Rationale for the present research

The literature shows that ASBI for young people has been successful for selected individuals, in certain settings. In particular, the current available evidence relates primarily to white, USA-based subjects, most often in educational settings and at the older end of the youth spectrum (see *Appendix 2*). However, there is currently insufficient evidence to be confident about the use of ASBI to reduce excessive drinking and/or alcohol-related harm in younger adolescents and in a school setting. Nevertheless, the current evidence base suggests that the most effective forms of BI are those containing personalised feedback about a young person's drinking behaviour and 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. This present work builds on the evidence base by focusing on ASBI to reduce hazardous drinking in younger adolescents (aged 14–15 years). It is highly likely that if a BI was effective at reducing hazardous drinking, it might also result in a range of other positive behavioural outcomes, as has been found in the adult literature as well as work with older adolescents.

Chapter 3 Development of intervention materials and training

Key points for Chapter 3

- Learning mentors were identified to be best placed within a school setting to deliver an intervention about alcohol. They were trained in study procedures and intervention delivery.
- The study incorporated control, intervention 1 and intervention 2 conditions, all manualised and designed to be delivered on a one-to-one basis to young people who screened positive for risky drinking and left their name on the questionnaire.
- Young people who were in control group schools met with the learning mentor who explained the study to them, and provided feedback that they may be drinking at a risky level, along with an alcohol information leaflet to take away and read.
- In addition to feedback and an alcohol information leaflet, young people allocated to intervention 1 took part in a 30-minute, six-step, interactive intervention led by the learning mentor.
- In addition to receiving intervention 1, young people who received intervention 2 were invited to attend a subsequent session with parental/family involvement, designed to last approximately 30–60 minutes, led by the learning mentor.
- Learning mentors were asked to record time spent with participants using open-ended case diaries.

Introduction

The present study incorporated control, intervention 1 and intervention 2 conditions. All three interventions were manualised to ensure consistency of delivery across schools allocated to that arm of the trial and reproducibility by other deliverers (see *Appendix 3*). Owing to availability of resources, all tools and manuals were provided in the English language only. All young people recruited into the trial, regardless of arm, continued to receive 'standard alcohol advice', delivered as part of the school curriculum. The first section of this chapter is concerned with defining what this consisted of in the study catchment area. In addition, young people in schools allocated to the control arm received feedback that they may be drinking at a risky level and an alcohol information leaflet. Young people in schools allocated to the intervention 1 arm took part in a 30-minute one-to-one structured intervention session with a trained learning mentor. In addition to receiving intervention 1, young people in schools allocated to the intervention 2 arm were invited to attend a subsequent session, facilitated by trained school staff, with parental/family involvement, designed to last approximately 30–60 minutes. Young people from schools allocated to intervention 1 and intervention 2 received the same alcohol advice leaflet as those allocated to control. All young people recruited into the trial were followed up 12 months post intervention.

The rest of the chapter describes the design of intervention materials, as well as the training and support provided to learning mentors in the delivery of interventions. The rationale behind, and development of, each intervention condition (control, intervention 1, intervention 2) is detailed, and the outcomes of piloting of materials and consultation with key groups (parents and young people) are outlined with any resultant modifications to intervention materials reported.

Defining 'standard alcohol advice'

In order to fully understand the control context, it was first important to determine the scope of 'standard alcohol advice' received by all young people aged 14–15 years at secondary school (Years 10 and 11). Provision of classroom-based drug and alcohol education continues to be recognised as an important aspect of the secondary school curriculum (for those aged 11–16 years) for England, Scotland and Wales, and is generally tackled within PSHE classes. PSHE is non-statutory yet the provision of high-quality PSHE forms a significant part of the Office for Standards in Education, Children's Services and Skills (OFSTED) inspections and contributes to the statutory responsibility of schools to 'promote children and young people's personal and economic well-being; offer sex and relationships education; prepare pupils for adult life and provide a broad and balanced curriculum',¹⁵⁰ delivered as part of a wider 'well-being' remit through the National Healthy Schools Programme¹⁵¹ and the Social and Emotional Aspects of Learning (SEAL) strategy.¹⁵¹

However, there are no prescriptive guidelines on what PSHE should actually entail, as long as it encompasses these wider statutory responsibilities. As a result, schools have developed their own versions of PSHE, and different ways to deliver it, rather than following standardised frameworks of study.¹⁵⁰ Our observations mirror this and the research team recorded different PSHE arrangements in each of the participating schools. For example, several schools timetabled weekly lessons dedicated to PSHE topics, sometimes described as 'citizenship' or 'extended tutorial'. One participating school had no PSHE provision and instead timetabled a 'health day' once per academic year. Schools were also able to elect a key 'well-being' focus for the coming academic year. Thus, if they chose to elect alcohol rather than another area (such as self-harm or sexual health) then this could feasibly have an impact on educational provision. Thus, the control context was a highly variable condition, with 'standard alcohol advice' defined in this study as the regular provision of classroom-based alcohol education to Year 10 pupils as delivered at each particular school site.

School staff identified to deliver interventions

Learning mentors are specifically trained to provide a service complementary to that of teachers and other school staff, addressing the needs of children who require assistance in overcoming barriers to learning in order to achieve their full potential. All secondary schools have learning mentors working in them. They work with a range of pupils, but give priority to those who need the most help, especially those experiencing multiple disadvantages. Mentoring covers a wide range of issues, from punctuality, absence, bullying, challenging behaviour and abuse to working with able and gifted pupils who are experiencing difficulties. Learning mentors support, motivate and challenge pupils who are underachieving. They help pupils overcome barriers to learning caused by social, emotional and behavioural problems. Learning mentors need good listening skills and an understanding of health and social issues that affect children and young people's development. The mentors mainly work with children who experience 'barriers to learning', including poor literacy/numeracy skills, underperformance against potential, poor attendance, disaffection, danger of exclusion, difficult family circumstances and low self-esteem. Thus, learning mentors were thought to be most well-placed within a school setting to deliver an intervention to young people about alcohol use.

Local areas vary in their essential qualifications for appointment for learning mentors. However, as a minimum, they need to have a good standard of general education, especially literacy and numeracy, as well as experience of working with young people. Within the present study, learning mentors were defined as the members of school staff trained in the delivery of the control condition/interventions to participating students. However, in practice, within each school, titles, roles and responsibilities varied, and this did not constitute a homogeneous professional group. Thus, for consistency, school staff responsible for the delivery of interventions are referred to only as learning mentors throughout the rest of this report.

Patient and public involvement: selecting an alcohol information leaflet (control)

All young people recruited into the trial were provided with an alcohol advice leaflet. It was important that this leaflet was age appropriate (for 14- to 15-year-olds) and suitable for use in a school setting, yet with a presentation style favoured by young people. Owing to time and resource constraints, it was not feasible for the study team to design a new alcohol information leaflet. Instead, we reviewed a large amount of national and regional resources (including materials from the Department of Health, NHS Choices, Home Office, Talk to FRANK, Change4Life, 'Know Your Limits' and resources from local youth drug and alcohol services) and liaised with experts in the field. Two appropriate packs or leaflets were sourced, both designed by the Comic Company (www.comiccompany.co.uk/: the 'Cheers! Your Health' alcohol leaflet, and 'snapper', a quiz question folding game). Both leaflets were discussed with colleagues at Newcastle University, who are experts in working with young people in the school setting and who supported their use. Following this, they were piloted during five focus groups held with young people from years 9–11 (aged 13–16 years) at participating schools.

Young people across all focus groups agreed that the 'Cheers! Your Health' alcohol leaflet and 'snapper' resources were suitable for young people aged 14–15 years, and these materials were selected as alcohol advice leaflets and provided to young people in all arms of the pilot trial (see *Appendix 3*). In particular, young people indicated that encouraging them to engage with anything in a non-pictorial way would be challenging. Young people wanted the information presented to them in a fun or humorous way, without too much text, and liked leaflets to include games or puzzles. In particular, positive comments about the 'Cheers! Your Health' leaflet included that it was 'detailed', 'interesting' and 'interactive'.

Young people who were in the control group schools met with the learning mentor who explained the study to them. The young people were told that they may be drinking alcohol in a way which may be harmful to them. Once consented to the study the young people were given the alcohol leaflets mentioned above to take away and read.

Development of intervention 1

The intervention 1 session was a manualised intervention, which combined simple structured advice and behaviour change counselling techniques commonly used within the extended BI. The tool was a colourful, six-step intervention, intended to be an interactive discussion between the young person and the learning mentor (see *Appendix 3*). It sought to increase awareness of risks and enable the young person to consider their motivations for changing their alcohol use. The intervention was designed to last approximately 30 minutes and take place in the learning mentor's office or alternative suitable space. It was expected that young people would be taken out of class to attend appointments with learning mentors. The rest of this section details each step of the intervention tool in turn. Intervention 1 consists of six sections.

Intervention 1

Section one: how many units are in my drink?

This section sought to raise the young person's awareness of the units of alcohol contained in drinks that are commonly consumed by young people. It was similar to the information commonly provided in simple structured advice.¹⁵² Young people were encouraged to calculate the number of units that they drank during a typical drinking day. This calculation was then used as a basis for discussing the recommended levels for adults and the Chief Medical Officer's (CMO's) recommendation that young people aged < 15 years do not drink alcohol at all and to enable personalised feedback about the risks associated with the young person's drinking. The young person was also asked to consider how common alcohol use is by young people aged 14–15 years. Learning mentors then advised the young people

of the actual numbers before asking young people to reflect upon their thoughts about this. This component was informed by social learning theory.⁵⁶ This information was delivered in accordance with the elicit–provide–elicit approach to informing within MI.

Section two: typical drinking day

Young people were asked to discuss their typical drinking day in more detail within this section of the intervention. This background description was intended to provide a useful context for the ensuing discussion about the young person's drinking, associated risk and change. The typical drinking day was informed by the SIPS Brief Lifestyle Counselling (BLC) structure (www.sips.iop.kcl.ac.uk/blc.php). It was developed to provide greater structure and useful prompts about drinking behaviour (with, where, because) for both the young person and the learning mentor. In particular, the additional prompts were intended to provide information that might have been useful in the identification of risk (e.g. when a young person consumes alcohol this may increase or decrease risk), as well as reinforce positive drinking behaviours (e.g. times when young people drink in ways that are not risky) and the behaviours that may become the focus of change.

Section three: are there any risks with my drinking?

Section three of intervention 1 built upon section two and encouraged the young person to consider the risks associated with their alcohol use. The intention was that, by asking the young person to identify risks relevant to him/her, the young person would begin to identify motivation for change. It was expected that this would lead naturally on to how important it is for the young person to change their drinking. Young people were then advised of the common risks associated with drinking above CMO recommendations before being asked to reflect upon this in relation to their own drinking. As well as acting as a further prompt to identifying risks relating to their drinking, the delivery of this information was again in accordance with the elicit–provide–elicit approach to informing within MI.

Section four: importance/confidence

Section four encouraged the young person to rate the importance of changing his/her drinking and confidence in ability to change using a scaling question. Importance scales are used within behaviour change counselling in order to elicit change talk and assess readiness to change.¹⁵³ By prompting the young person to consider what would need to happen in order for this number to increase, ratings may also be positively affected and motivation developed. Confidence scales are useful in identifying barriers to change. Exploration around this can enable the young person to find ways to overcome these barriers and assist in the development of a coping plan in section six.

Section five: what do I think about reducing my drinking?

Section five asked the young person to consider the 'bad' and the 'good' things about reducing their drinking. This is comparable to the 'pros and cons of changing your drinking', which is included in the extended BI tool (www.sips.iop.kcl.ac.uk/blc.php) and discussed by Rollnick *et al.*¹⁵³ The terminology 'pros and cons' was changed to 'bad and good' to make the language more age appropriate.

Section six: what could I do about my drinking?

The final section of intervention 1 was concerned with developing an action plan and coping plan for change. It was acknowledged that not all young people will want to agree to making such a plan. For those who did, it was expected that the young person would set his/her own goals, facilitated by the learning mentor, based upon the content of the MI. The purpose of this section of the intervention was to elicit commitment talk from the young person,¹⁵⁴ as well as identifying existing life skills and developing coping strategies to enable young people to achieve and maintain change. Learning mentors employed a strengths-based approach wherein self-efficacy is promoted.

Development of intervention 2

Although BIs are mostly delivered on a one-to-one basis, intervention 2 sought to build upon the rationale for intervention 1 by involving parents. Young people from schools allocated to intervention 2 received an individual BI (intervention 1), followed by a group family intervention based on MI principles held approximately 1 month after.¹⁵⁵ By involving parents within a family intervention, the approach focused upon the dynamic between the individual, attitudes and the environment.⁵⁶ Indeed, the addition of a family intervention has elsewhere been found to improve drinking outcomes in adolescents at follow-up.¹⁰³

Intervention 2 was a manualised intervention based upon the principles of MI. It was intended to be a discussion that built upon intervention 1 described above, wherein the young person and the learning mentor explored the young person's drinking and their motivation for change. Intervention 2 sought to build upon the young person's motivation by encouraging the parents/family members to share their thoughts about the young person's drinking. The young person and the parents/family member were then encouraged to consider an action plan for change. The intervention was designed to last approximately 30–60 minutes (see *Appendix 3*). At the end of the session parents were provided with a parenting information leaflet about young people and alcohol use. It was expected that this session would take place either during or after school hours, either within the school or in a community centre nearby, and would take place only if the young person consented to parental involvement and parents subsequently agreed to take part. Intervention 2 consisted of four sections.

Intervention 2

Section one: review of first session

Similar to techniques used within motivational enhancement therapy, section one provided a review of the first session. It was preferable if this review was led and delivered by the young person in order to promote an empowering child-centred approach to the family intervention. However, if the young person felt unable to do this, the learning mentor would summarise the content of intervention 1. Using the intervention 1 sheet, it was expected that the review of the first session would reinforce the young person's motivation, by emphasising change talk.¹⁵⁴ It also provided background information for the parents/family members to inform the ensuing discussion about the young person's drinking, associated risk and change, and the parents'/family members' concerns about this.

Section two: what concerns you about your child's drinking?

Section two of intervention 2 built upon section one and encouraged the parents/family members to share any concerns they have about their child's drinking. It was intended that by asking the parent to share their feelings, the young person would begin to consider their drinking from another person's perspective, which would build upon their current motivation for change. It was expected that this would lead naturally on to a discussion about how important it was for the young person to change their drinking.

Section three: importance/confidence

Section three encouraged the parents/family members to rate (using a scaling question) the importance of their child changing their drinking and their confidence in their ability to help them to change. Although the importance scale was used in intervention 1 to assess the young person's readiness to change, within intervention 2 the aim is to develop further the young person's motivation. By prompting the parents/family members to share why they have rated the importance in a particular way, as well as what would need to happen in order for this number to increase, it was expected that both the parents/family members and the child's motivation to support and achieve change may be positively affected and motivation developed. Confidence scales are useful in identifying barriers to change. Specifically asking how confident the parents/family members feel in their ability to help the young person encourages a 'family approach' to change while also finding ways to overcome barriers and assist in the development of a coping plan in section four.

After identifying barriers and how confident parents/family members may feel about their ability to help the young person overcome these barriers, the learning mentor provided information detailed on the tool regarding the potential influence of parents/family members upon young people and their drinking, as well as the benefit of a supportive relationship. The learning mentors then asked parents/family members and the young person to reflect upon this and share their views. The delivery of this information was in accordance with the elicit–provide–elicit approach to informing within MI. It was also informed by the approach used within the Spirito *et al.*¹⁰³ study on family MI with alcohol-positive teenagers.

Section four: what could I do about my drinking?

The final section of intervention 2 was concerned with developing a family action plan and family coping plan for change. This was informed by the extended BI and the intervention manual for the family intervention used by Spirito.¹⁰³ It was acknowledged that not all families would want to agree to make such a plan. If they did, it was expected that the young person and parents/family members would negotiate these goals, facilitated by the learning mentor and based upon the combined content of interventions 1 and 2. The purpose of this section of the intervention was to elicit commitment talk¹⁵⁴ from the young person and parents/family members, enabling them to work together to agree an action plan and develop coping strategies to enable young people to achieve and maintain change.

The young person and parents/family members were encouraged to think of two or three good reasons for change. This was to reinforce motivation. They were then encouraged to set goals for change and, in doing so, evoke 'commitment talk'. It was expected that the learning mentor would explore the feasibility of these goals with all parties. The later part of the action plan was concerned with developing a coping plan. This was largely informed by the discussion, which developed from the confidence scale. Here the young person was asked about times or situations when change might have been difficult to achieve or maintain before then considering how they might deal with such times or situations. Planning for change in this way is assumed to be the most effective way to achieve and succeed. Through identifying by whom and how the young person may be supported in their efforts, the parents/family members were afforded an opportunity to support and encourage the young person. This also allows families to plan for and celebrate success.¹⁰³

Patient and public involvement: piloting of interventions

Interventions 1 and 2 were piloted with one young person and their mother by the research interventionist who had experience in MI techniques (December 2011 and February 2012, respectively). The intervention 1 session lasted approximately 25 minutes, whereas the intervention 2 session lasted approximately 45 minutes. The young person suggested adding information about calories to the intervention 1 tool as a way of making information about alcohol use more memorable and pertinent to young people. In particular, they suggested that they would have found this to be an effective motivator to changing drinking behaviour. A focus group was also held, in February 2012, with a convenience sample of four female parents, to discuss the intervention 2 tool, as well as anticipated methods for contacting parents to take part in the intervention. In particular, this group highlighted that the initial approach of school staff would be very important when introducing the project to parents for the first time over the telephone.

Modifications to the intervention materials as a result of piloting and consultation

As a result of piloting and consultation, the following modifications were made to intervention tools and materials:

- Provision of information about calories on the intervention 1 tool. The number of calories in popular food items (depicted using pictures) was mapped against alcohol brands and quantities that were popular with young people.
- A slight change to the guidance that was provided to school staff in relation to contacting parents for the first time about taking part in intervention 2. Specifically, the importance of non-judgemental language was reinforced with the learning mentors.

Training and support

All learning mentors received training prior to commencing the study. The training was split into four sessions, with each session lasting a minimum of 1 hour and a maximum of 3 hours. PowerPoint 2010 slides (Microsoft Corporation, Redmond, WA, USA) were used to guide each training session. An intervention manual relevant to each arm of the trial was provided to supplement the training (see *Appendix 3*).

Training was conducted in a community venue or school, as outreach training has been found to be the most cost-effective implementation strategy for ASBI delivery in other settings.¹⁵⁶ The training was jointly delivered by an experienced interventions trainer and researcher, using training materials that were customised for the school setting. A total of 27 learning mentors across the seven schools were trained by the research team. The biggest individual school team of learning mentors comprised nine members of staff, whereas the smallest had two members of staff.

The first training session was delivered to learning mentors from all seven schools as a group to raise awareness of the risks associated with young people drinking and to introduce the study. The training included a PowerPoint presentation, group discussion and simulated young-person scenarios. Learning mentors were also trained to issue the participant information leaflet, gather informed consent from the young person, and deliver the alcohol information leaflet (control intervention). This concluded the training for learning mentors from schools allocated to the control intervention arm of the trial who, in order to prevent contamination, received no training on interventions 1 or 2.

Learning mentors at schools randomised to intervention 1 and 2 were then trained to deliver intervention 1. Again, learning mentors were trained together as a group. In addition to a PowerPoint presentation, training consisted of a demonstration of how to deliver the intervention and simulated young-person scenarios. Learning mentors randomised to intervention 2 were asked to return for a further half-day training session. For intervention 2, training sessions were delivered per school site, as a training date could not be identified which accommodated all learning mentors. This session trained learning mentors in how to gather informed consent from parents for the intervention and organise and facilitate intervention 2, as well as how to respond to difficult disclosures.

The final training session focused on delivery of the 12-month follow-up appointment. Training consisted of a PowerPoint presentation and a demonstration of how to deliver each of the measures included in the follow-up assessment. All learning mentors received the same training; however, training sessions were delivered per school site, as a training date could not be identified which accommodated learning mentors from all participating schools. A manual relevant to the 12-month follow-up appointment was provided to supplement the training (see *Appendix 3*).

Learning mentors were supported in the delivery of interventions and follow-up appointments by the research team, who organised weekly visits throughout the study period to answer questions or concerns, collect materials from completed interventions (such as consent forms and hard copies of intervention tools) and encourage learning mentors to complete outstanding interventions. The research team also provided telephone and e-mail support. Finally, learning mentors were provided with a case diary sheet, on which they were asked to record any interactions with the individual young people in the trial (see *Appendix 3*). A main resource-use component of the economic evaluation (for the larger definitive trial) will be the cost of learning mentor time required to prepare for and conduct interventions and follow up with the young people during the trial. Thus, time spent for the present study was calculated by observing the average minutes per case, as documented in self-completed case diaries. The appropriateness of the case diary tool for collecting these data was assessed according to rates of missing data (incomplete or wholly unused diaries) and of diaries missing relevant information (see *Chapter 7*).

Chapter 4 Survey

Key points for Chapter 4

- Seven schools took part in a set of three cross-sectional surveys administered at baseline (TP1), 6 months (TP2) and 12 months (TP3). Surveys administered at TP1 facilitated screening for the pilot trial.
- Six per cent ($n = 87$) of parents indicated that they did not wish their child to take part in the study by completing and returning a tick-box opt-out form.
- Survey response rates among pupils whose parents allowed them to take part were 92% at baseline (TP1), 90% at 6 months (TP2) and 84% at 12 months (TP3).
- Levels of missing data were low for all variables.
- A comparison of the distributions of AUDIT and AUDIT-C scores between subgroups at TP1 demonstrated that gender, smoking and sexual behaviour were significantly associated with young people's current drinking behaviour.
- Mean AUDIT scores were higher for young people who did not leave their names on the questionnaire than for those who did.
- Comparison of scores over three time points suggests there was little or no change in measures of alcohol use, alcohol-related problems and well-being within this age group over the course of a year, except for small but statistically significant shifts upwards in the distributions of AUDIT, AUDIT-C and A-SAQ scores between the first and second surveys.

This chapter reports the methods and results of a set of three cross-sectional school surveys, administered at baseline (TP1), at 6 months (TP2) and at 12 months (TP3).

Methods

Recruitment of school sites

Written approval was obtained from the relevant local education authority, stating that it was willing for the project to go ahead in the study catchment area. All secondary/high schools in the study catchment area governed by the relevant local authority were eligible to take part in the study. Contact details for each school were provided by the local education authority. Contact from the research team with each school site was initially made by telephoning and e-mailing the school office and securing appropriate points of contact, such as the Head or Deputy Head (of Year 10 or the whole school) and pastoral leads. These individuals are described here and throughout this report as 'lead liaisons' and are defined as the key member of staff at each school site who made or brokered the decision about participation in the study on behalf of their school.

During an initial meeting between the research team and lead liaisons, the study protocol was explained and lead liaisons were provided with a short written outline of the study in an attempt to secure school participation. A written outline was provided, as it was anticipated that lead liaisons would need to share details of the study with other members of the school management team, such as head teachers (if not already the point of contact) or the board of governors. Final approval to participate in the study was then obtained from the head teacher on behalf of the school and board of governors at each school, and communicated by the school lead liaison to the research team verbally or by e-mail. A second visit was arranged by the research team to all participating schools in order to organise screening of Year 10 pupils and training for school staff who had responsibility for the delivery of interventions. Each school site received a £1000 payment to cover costs associated with the research.

Recruitment of pupils

In advance of the study, all parents/legal guardians of young people in Year 10 at participating schools were informed by letter that the study would be taking place in their child's school (see *Appendix 3*). Letters were addressed on site at each participating school and posted directly to parents. Letters included a prepaid return envelope, addressed to the research team at the Newcastle University. Parents were given the option to indicate that they did not wish their child to take part in the study by completing and returning a tick-box opt-out form. Parents were asked to return this form within 2 weeks of the date shown on the letter. Returning this form to the research team resulted in their child not being included in both the survey and the pilot trial. No further parental consent for young people's participation was sought. An opt-out process, rather than opt-in, was chosen, as sending letters home in order to obtain permission from parents for all young people to fill in a screening survey (and potentially take part in the trial) ran the risk of bias in recruitment and the potential loss of a large number of participants. An opt-out process was supported by the local education authority in the study catchment area, who advised that collection of health and lifestyle data without parental opt-in was a routine approach in school settings. Further, collection of questionnaire data in schools without parental opt-in is a method widely used in various national youth surveys of alcohol consumption and other health behaviours, such as those conducted by the NHS Information Centre annually exploring drinking and drug use by young people aged 11–15 years in England and Wales.⁴

All Year 10 pupils at participating schools, except those whose parents had opted out of the research, were asked to complete a health and lifestyle questionnaire administered during a predefined school lesson falling in the week that the survey was due to take place. Pupils were asked to complete the questionnaire at three separate time points: TP1 (between November 2011 and January 2012), TP2 (6 months later: June and July 2012) and TP3 (12 months later: November and December 2012), by which time they were in Year 11. The research team provided support to school staff in implementing the survey tailored to the needs of the school setting. In advance of the survey, packs containing the correct number of survey materials were delivered to each school. The lead liaison in each school was actively involved in setting the survey date. All surveys took place during tutorial or PSHE lessons. However, tutorials or PSHE lessons did not follow exactly the same format at each school and their duration ranged from 30 minutes to 1 hour or an entire day. A minimum of one researcher was present at each school site when surveys took place. At each time point, data collection predominantly took place across one day at each school. However, young people absent on the date of the survey were followed up by school staff to minimise missing data. If young people were opted out by their parents, class teachers provided them with an alternative task while their peers completed questionnaires (e.g. outstanding homework or computer-based research). Young people were informed at every survey that their involvement was voluntary and the survey could be completed anonymously. At TP1 young people were asked to indicate willingness to participate in the pilot trial by including their contact details on the questionnaire. All young people who completed the questionnaire at TP1 were provided with a healthy living leaflet and £5.00 retail gift voucher.

Questionnaire measures

Young people were asked to complete a series of questionnaires including the A-SAQ, a modified version of the M-SASQ (Modified-Single Alcohol Screening Question),¹⁵⁷ which aims to identify whether an individual's drinking is above low risk, with the quantity/frequency measures adjusted to reflect guidelines for an adolescent population of half the adult daily limits (three units).²⁶ Young people were asked 'In the last 6 months how often have you drunk more than three units of alcohol?' with the response options of 'Never', 'Less than four times', 'Four or more times but not every month', 'At least once a month but not every week', 'Every week but not every day' and 'Every day'. The A-SAQ contained pictorial references of what constitutes a unit of alcohol. A score of 'four or more times', or more frequently, indicated a positive screen and was indicative of being potentially eligible for inclusion in the trial.

The survey also included a general lifestyle questionnaire addressing a number of questions (diet, smoking, sexual behaviour and exercise) that were taken from the European school Survey Project on Alcohol and other Drugs (ESPAD) study³ and the Gateshead Millennium Study.¹⁵⁸ The 14-item WEMWBS was used to assess general psychological health.¹⁵⁹ The tool uses a five-point Likert scale, which gives a score of '1–5'

per question, giving a minimum score of '14' and maximum score of '70'. A higher WEMWBS score indicates a higher level of mental well-being.¹⁶⁰ It has been shown to be valid and reliable with young people aged ≥ 13 years in England.¹⁶¹ As well as the A-SAQ, alcohol use frequency, quantity (on a typical occasion) and heavy episodic drinking was also assessed using the 10-question AUDIT,¹⁶² with cut-offs recommended for adults (8+)¹⁶² and young people (2+),⁵⁰ as well as a positive score for the AUDIT-C screen of 5+ used for adults (see *Chapter 2, Primary and secondary prevention interventions for risky drinking*). Alcohol-related problems were assessed using the validated 23-question RAPI tool, which includes measures on aggression.¹⁶³ The RAPI has been well validated for use with both clinical and community adolescent samples.^{163,164} The EQ-5D-Y, which is a recently developed young-person version of the EQ-5D, was used to assess health-utility scores.¹⁶⁵ It is a quality of life measure used extensively in economic evaluations. The tool divides health status into five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Each of these dimensions has three possible levels giving 243 possible health states.¹⁶⁵ A modified S-SUQ was used to inform the health and social resource costs for any future economic evaluation.¹⁶⁶ Finally, demographic information (gender and ethnicity) was collected from each pupil who completed a questionnaire. Young people were asked to place their questionnaire in a blank envelope, which they sealed themselves and handed to the teacher. The young person had the option of inserting a completed questionnaire with or without their name or a blank questionnaire into the envelope.

Statistical analysis

For all variables the percentage of missing and implausible values was reported, along with either a five-number summary (minimum, lower quartile, median, upper quartile, maximum) for numeric variables, or percentages in each category for categorical variables. Details of the scoring system for numeric scales are given in *Appendix 5*.

Descriptive analysis

The survey variables are reported separately at the three time points (TP1, TP2 and TP3). For all of the variables we report the number of observations and percentage of missing and implausible values. In addition, five-number summaries are reported for the numeric variables, and the distributions of categorical variables are reported as percentages.

Comparisons between subgroups of young people at time point 1

For the TP1 survey data, AUDIT and AUDIT-C scores were compared by subgroups of gender, smoking status and sexual behaviour. Smoking status and sexual behaviour were of interest to see if those young people who displayed risky drinking behaviour were also more likely to take risks in other lifestyle choices. Three different cut-off points are used to compare the distribution of AUDIT and AUDIT-C scores (a score of 2+ or 8+ for AUDIT, and a score of 5+ for AUDIT-C). Differences between scores were tested using Mann–Whitney and Kruskal–Wallis analysis of variance tests as appropriate. Correlation coefficients were calculated for AUDIT and AUDIT-C scores with RAPI and WEMWBS to explore the association between drinking, well-being and alcohol-related problems.

Comparisons of results of surveys at different time points

To investigate any change over the 12-month period in drinking behaviour, alcohol-related problems and quality of life, a comparison of the distribution of A-SAQ, AUDIT, AUDIT-C, RAPI and WEMWBS was made at all three time points (TP1, TP2 and TP3). Data from the three time points were regarded as being independent, as the young people did not leave their names in TP2 and TP3, and so measures were analysed using Kruskal–Wallis tests. If significant differences were established across the three time points for a given variable, formal comparisons between the pairs of consecutive time points (TP1 and TP2; TP2 and TP3) were made using Mann–Whitney *U*-tests.

Comparison of named and anonymous pupils

For each school, the number of young people completing questionnaires was reported and the percentage of those young people who provided their names was calculated. Differences in percentages scoring positive for A-SAQ and differences in mean AUDIT scores were calculated for those who provided their names and those who did not, in order to establish if there was a difference in drinking behaviour between these groups.

Distribution of missing values within questionnaires

If an individual item was missing from within a questionnaire, this meant that the overall questionnaire score was also missing. To investigate whether there were particular items that were more often missing, a breakdown of missing data by question was provided for the AUDIT, RAPI and WEMWBS questionnaires.

Results

Recruitment and retention

The local education authority provided accurate pupil numbers for Year 10 for the seven schools participating in the study. There were 1388 young people across all seven schools that could feasibly complete the survey at TP1. On the days that the surveys were to be completed there were differing numbers of young people absent from school, making the final numbers of completed surveys 1280 at TP1, 1256 at TP2 and 1161 at TP3 (Figure 2).

Table 1 shows the number and percentage of young people who completed the questionnaire on the prearranged day and the number and percentage followed up in the days following.

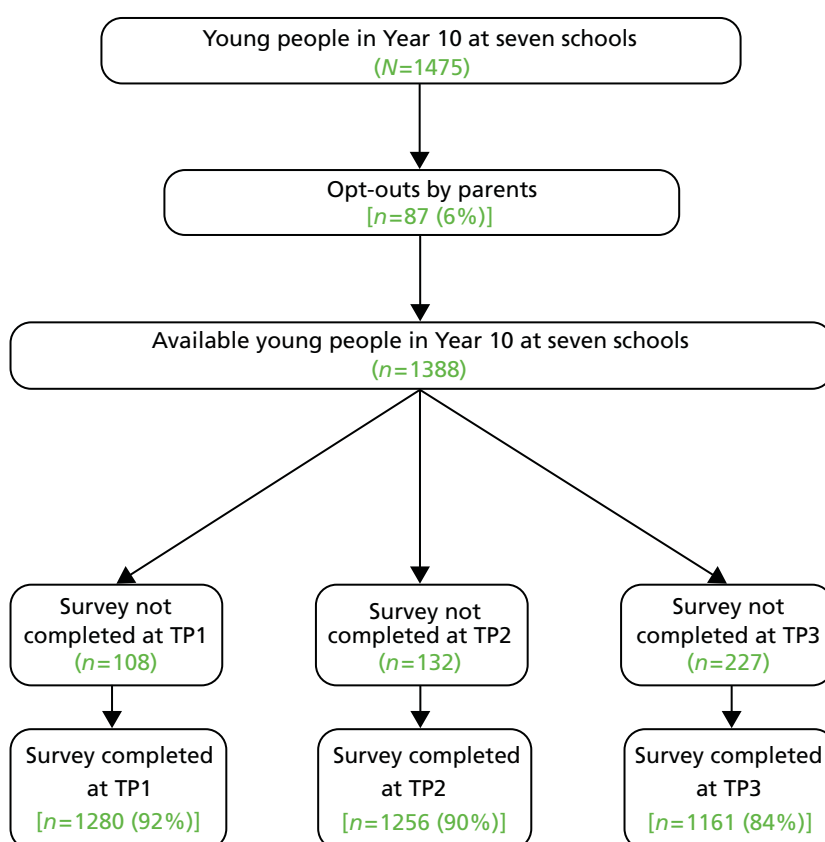


FIGURE 2 Completion of surveys at all three time points (TP1, TP2 and TP3).

TABLE 1 Questionnaire completion by young people on day of survey (TP1, TP2 and TP3)

Time point	Initial survey		Collected after initial survey ^a	
	<i>n</i>	%	<i>n</i>	%
1	1178	92.0	102	8.0
2	1139	90.7	117	9.3
3	1028	88.5	133	11.5

^a Young people missing on day of survey who completed the questionnaire at a later date.

Missing data

Descriptive statistics for numeric variables in the survey are reported in *Table 2*. Levels of completion across all three time points were high. There were 80 missing responses for WEMWBS and only one missing response for AUDIT score at this time point. WEMWBS also had the most missing values at TP1 and TP2. At TP1 and TP2, levels of missing data ranged from 1% and 2% (AUDIT), respectively, and from 12% to 13% (WEMWBS). The WEMWBS scale was the last set of questions in the survey pack, which may explain the higher rate of missing data.

TABLE 2 Summary of numeric variables for whole year groups at TP1, TP2 and TP3

Measure (potential scale range)	<i>N</i>	Missing (%)	Implausible values (%) ^a	<i>n</i> available	Minimum	Lower quartile	Median	Upper quartile	Maximum
AUDIT (0–40)									
TP1	1280	6.0	–	1203	0	0	2	8	40
TP2	1256	6.4	–	1176	0	1	4	8	40
TP3	1161	0.1	–	1160	0	1	4	9	40
AUDIT-C (0–12)									
TP1	1280	5.6	–	1208	0	0	2	4	12
TP2	1256	5.3	–	1189	0	1	3	5	12
TP3	1161	3.3	–	1123	0	1	3	5	12
RAPI (0–69)									
TP1	1280	5.6	–	1208	0	0	1	6	69
TP2	1256	7.7	–	1159	0	0	1	6	69
TP3	1161	4.1	–	1113	0	0	1	6	69
WEMWBS (14–70)									
TP1	1280	11.6	–	1132	14	42	48	55	70
TP2	1256	13.1	–	1091	14	42	49	55	70
TP3	1161	6.9	–	1081	14	41	49	55	70
Physical activity last week (0–7)									
TP1	1280	8.8	6.1	1089	0	2	4	5	7
TP2	1256	5.9	6.1	1106	0	2	4	5	7
TP3	1161	4.7	6.5	1031	0	2	3	5	7

continued

TABLE 2 Summary of numeric variables for whole year groups at TP1, TP2 and TP3 (*continued*)

Measure (potential scale range)	N	Missing (%)	Implausible values (%) ^a	n available	Minimum	Lower quartile	Median	Upper quartile	Maximum
Physical activity usual (0–7)									
TP1	1280	7.0	6.2	1112	0	2	4	5	7
TP2	1256	5.3	4.8	1130	0	2	4	5	7
TP3	1161	3.4	4.7	1068	0	2	4	5	7
Fruit (0–14)									
TP1	1280	3.0	0.8	1232	0	1	2	3	12
TP2	1256	3.4	0.9	1202	0	1	2	3	12
TP3	1161	1.6	0.6	1136	0	1	2	3	12
Vegetables (0–22)									
TP1	1280	5.8	0.8	1196	0	1	2	3	15
TP2	1256	4.5	0.5	1176	0	1	2	3	20
TP3	1161	2.8	0.6	1121	0	1	2	3	20
^a Implausible values were those that were impossible (> 7 days of physical activity in a week) or seemed to be unlikely or more extreme than the answers the majority of young people had given (> 14 portions of fruit and > 22 portions of vegetables).									

There were similar low levels of missing data for the main categorical variables reported in *Table 3*, ranging from 0.1% for gender at TP3 to 4.5% for the question about sex without a condom at TP2. Again, there were no missing values reported for the questions relating to how free time was spent, as these were tick boxes for positive answers, and a blank could indicate either that they did not take part in that activity or they had not answered the question. However, there were 42 (3.3%) young people who did not tick any boxes at TP1, 44 (3.5%) at TP2 and 62 (5.3%) at TP3.

Analysis of time point 1 data

Distribution of AUDIT and AUDIT-C scores

Figure 3 shows the distribution of the AUDIT and AUDIT-C scores for the whole sample. Scores had a positively skewed distribution, with 340 (28.4%) and 341 (28.2%) individuals scoring the minimum on AUDIT and AUDIT-C, respectively. Scores were recorded up to the maximum of the scales, with three (0.3%) young people scoring the maximum on AUDIT and 10 (0.8%) on AUDIT-C. The median AUDIT score was '2' and the mode was '0' (never drink); the median for AUDIT-C was '2' with a mode of '0'. The figures also illustrate the differing proportions of young people who would be categorised as 'positive' using suggested cut-off values for adults (8+) and young people (2+).

Twenty-six per cent ($n = 307$) of the sample had an AUDIT score of ≥ 8 (the cut-off used for determining alcohol use disorders in adults)¹⁶² and 58% ($n = 691$) scored ≥ 2 (the modified cut-off suggested for adolescents).⁵⁰ In addition, albeit using a breakdown designed for use with adults, 28% scored '0' and could be categorised as 'abstainers'; 46% 'lower risk' (1–7); 18% 'increasing risk' (8–15); 4% 'higher risk' (16–19); and 4% 'possible dependence' (20+) on the full AUDIT. Twenty per cent ($n = 245$) of the sample screened positive for hazardous or harmful drinking using a cut-off of '5' on AUDIT-C.

TABLE 3a Summary of distribution of alcohol-related categorical variables for whole year groups at three time points (TP1, TP2 and TP3)

Variable	Distribution over categories ^a by time point (%)		
	TP1 (n = 1280)	TP2 (n = 1256)	TP3 (n = 1161)
AUDIT: above suggested cut-off points			
% participants scoring ≥ 2 (adolescents) ^b	58.1	66.1	68.8
% participants scoring ≥ 8 (adults) ^c	26.0	29.3	31.8
AUDIT-C: above suggested cut-off points			
% participants scoring ≥ 5 (adults) ^c	20.7	29.1	32.6
A-SAQ (over last 6 months)			
Missing (%)	14 (1.1)	24 (1.9)	4 (0.3)
Never	35.2	27.8	28.7
Fewer than four times	25.5	25.4	24.6
Four or more times but not every month	11.7	14.7	15.0
One or more per month but not every week	13.9	16.1	16.3
Every week but not every day	12.6	14.0	13.6
Every day	1.0	2.0	2.0
% with positive score ^d	39.3	46.8	46.7
Sex regretted after alcohol			
Missing (%)	38 (3.0)	52 (4.1)	22 (1.9)
Never had sex	63.7	56.9	52.7
Yes	8.1	10.3	13.6
No	28.3	32.8	33.7
Sex without condom after alcohol			
Missing (%)	40 (3.1)	56 (4.5)	21 (1.8)
Never had sex	64.5	57.5	53.0
Yes	7.9	10.3	12.8
No	27.6	32.3	34.2
^a Percentages calculated across categories of each variable, excluding missing category. ^b Cut-off suggested for adolescents. ^c Cut-off suggested for adults. ^d At least four or more times but not every month.			

TABLE 3b Summary of distribution of non-alcohol-related categorical variables for whole year groups at three time points (TP1, TP2 and TP3)

Variable	Distribution over categories ^a by time point (%)		
	TP1 (n = 1280)	TP2 (n = 1256)	TP3 (n = 1161)
Gender			
Missing (%)	8 (0.6)	17 (1.4)	1 (0.1)
Male	49.5	48.7	47.8
Ethnic group			
Missing (%)	17 (1.3)	35 (2.8)	13 (1.1)
White	94.1	93.3	93.2
Smoker			
Missing (%)	44 (3.4)	38 (3.0)	33 (2.8)
Yes	19.6	24.6	23.1
Age when first smoked			
Missing (%)	33 (2.6)	25 (2.0)	14 (1.2)
Never	66.6	60.4	60.2
≤ 8 years	1.6	2.2	2.4
9–10 years	2.8	2.4	3.1
11–12 years	12.0	11.5	10.6
13–14 years	14.9	16.7	14.7
> 14 years	2.1	6.7	9.2
Use of free time^b			
With friends at your house or theirs	34.8	32.4	37.8
Go out somewhere with friends	60.6	62.3	54.1
Spend time with your family	17.5	13.9	17.1
Spend time with siblings	6.5	5.7	6.5
Spend time by yourself	21.8	21.3	23.8
a Percentages calculated across categories of each variable, excluding missing category. b There are no missing data for 'Use of free time', as these were tick-box questions – participants could tick multiple boxes or none.			

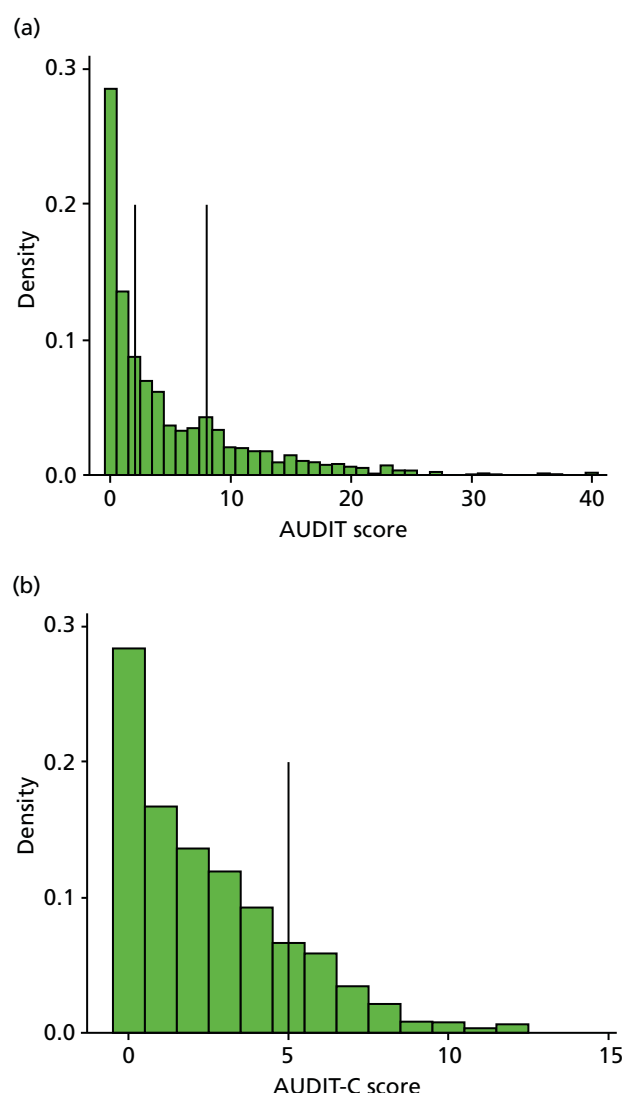


FIGURE 3 Distribution of the AUDIT score with (a) young person (score of '2+') and adult (score of '8+') cut-offs; and (b) AUDIT-C cut-offs (score of '5+').

Differences in AUDIT and AUDIT-C scores by gender

There was a difference in the distribution of AUDIT scores at TP1 by gender, with girls having a tendency to have higher scores (a median score of '3' in girls as opposed to '2' in boys). A similar shift in distributions was also seen for AUDIT-C scores, for which the median scores were '2' in girls as opposed to '1' in boys. This is illustrated in *Figure 4*. Mann–Whitney *U*-tests confirmed that these were statistically significant differences ($p < 0.0001$ and $p = 0.0005$, respectively).

Differences in AUDIT-C score by smoking status

There was a marked difference in the distribution of AUDIT scores by smoking status, with those who smoked having a tendency to have higher scores (a median score of nine in smokers compared with one in non-smokers). A similar shift in distributions was also seen for AUDIT-C scores, for which the median scores were '4' in smokers as opposed to '1' in non-smokers. This is illustrated in *Figure 5*. Mann–Whitney tests confirmed that these were statistically significant differences ($p < 0.0001$ for both tests).

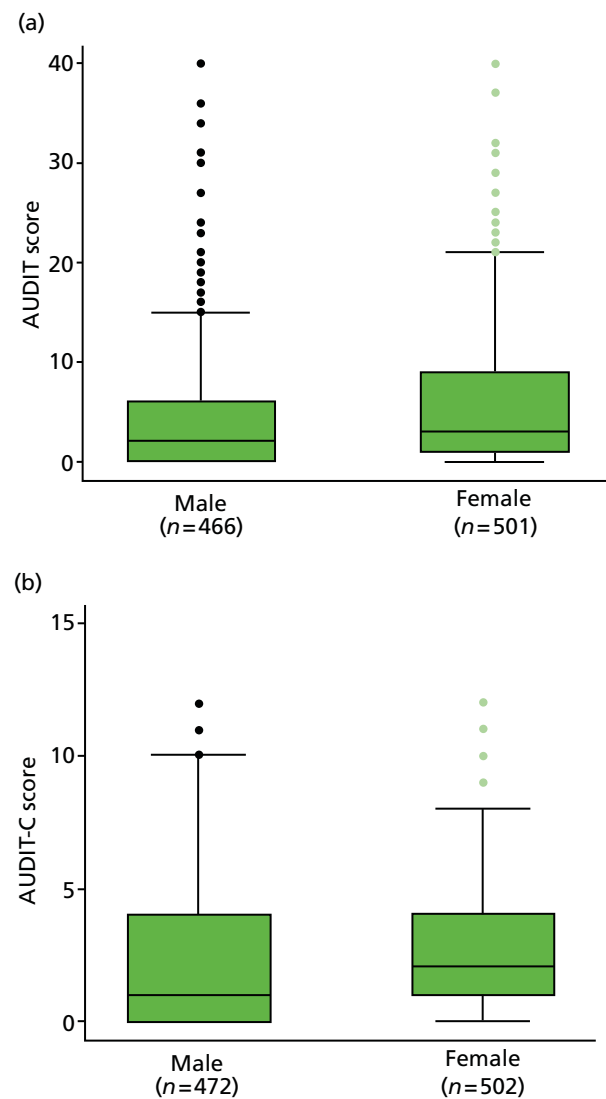


FIGURE 4 Distribution of AUDIT and AUDIT-C scores by gender. Box plots of (a) AUDIT score by gender; and (b) AUDIT-C score by gender.

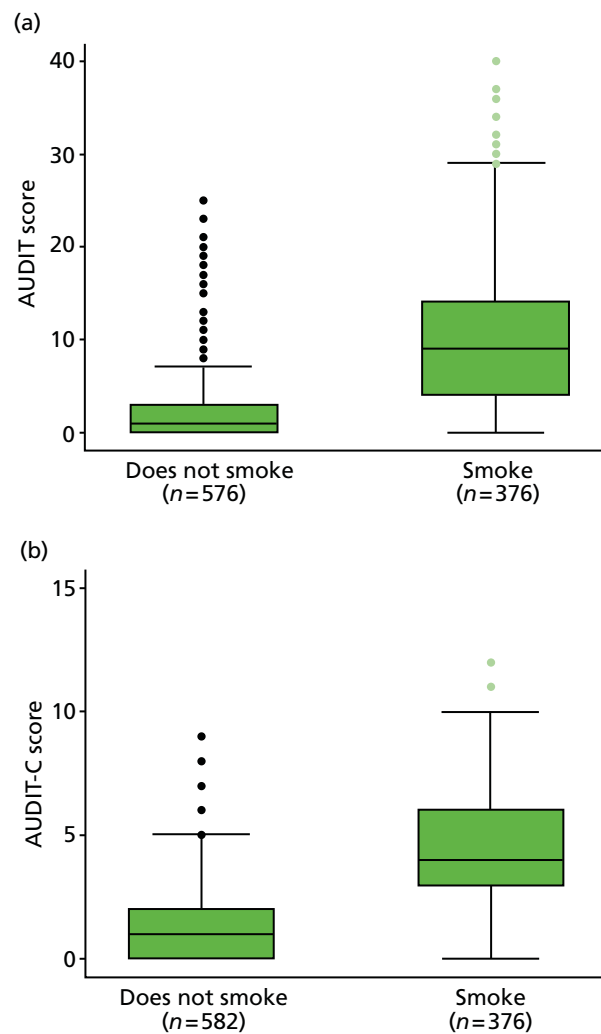


FIGURE 5 Distribution of AUDIT and AUDIT-C scores by smoking status. Box plots of (a) AUDIT score by smoking status; and (b) AUDIT-C score by smoking status.

Differences in AUDIT score by sexual behaviour

There was a marked difference in the distribution of AUDIT scores by sexual behaviour (measured here by use of condoms), with a tendency to have higher scores as the sexual behaviour was more risky. Young people were asked if they had ever engaged in sex without a condom after drinking alcohol, and the median score was '16' in those who had not used a condom after alcohol; '5' in those who had engaged in sex with a condom; and '1' in those who had never had sex at all. Note that those who had never had sex will include some young people who had not ever drunk alcohol. A similar shift in distributions was also seen for AUDIT-C scores, for which the median scores were '6' in those who had not used a condom, '3' in those who had engaged in sex with a condom, and '1' in those who never had sex. This is illustrated in Figure 6. Kruskal–Wallis tests confirmed that these were statistically significant differences ($p = 0.0001$ for both tests).

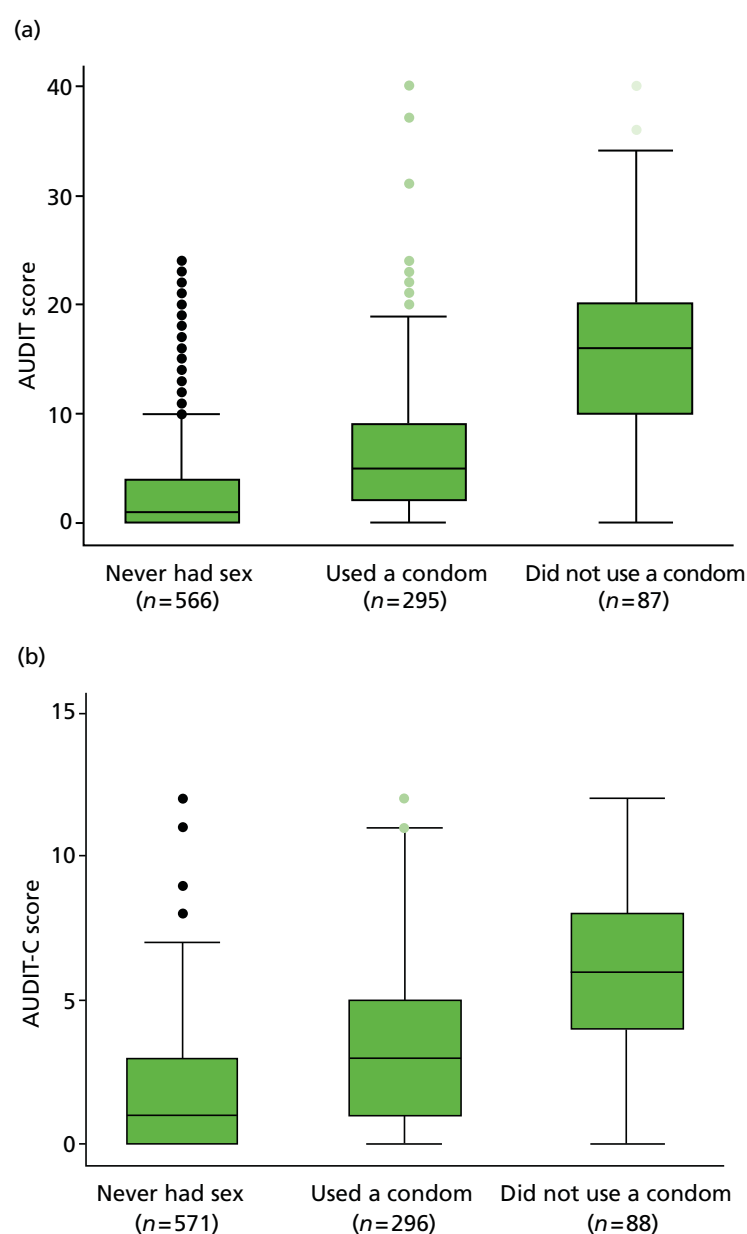


FIGURE 6 AUDIT and AUDIT-C scores by condom use. Box plots of (a) AUDIT score by condom use; and (b) AUDIT-C score by condom use.

Distribution of Rutgers Alcohol Problems Inventory and Warwick–Edinburgh Mental Well-being Scale scores

The RAPI score was calculated on only those who had drunk alcohol and had a positively skewed distribution with a median of '2' ($n = 877$). Six hundred and two (50%) individuals scored '0' and three (0.3%) scored the maximum of '69'. The WEMWBS score was calculated for all young people who completed the measure and had a median of '48' ($n = 1123$). This is comparative to other studies with young people aged 13–16 years (median '49').¹⁶¹ Twelve young people scored the minimum of '14' (1.1%) and 21 (1.9%) the maximum of '70'. The distributions of these two variables are shown in *Figure 7*.

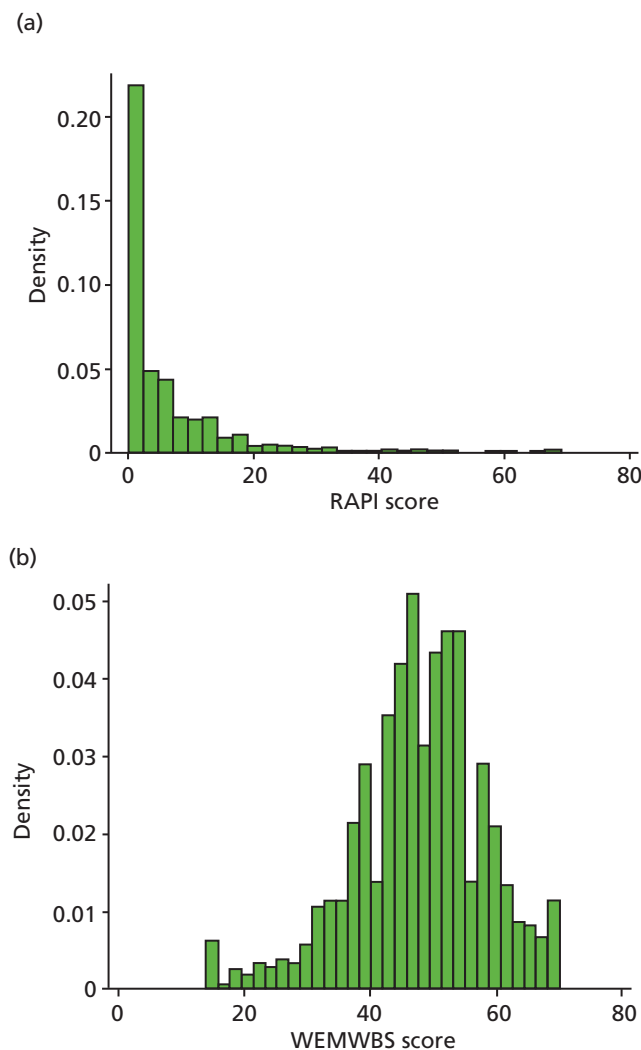


FIGURE 7 Distribution of RAPI and WEMWBS scores. Histograms of the distribution of (a) the RAPI score excluding those who never drink alcohol; and (b) the WEMWBS.

Associations between measures at time point 1

The strength of association between AUDIT, AUDIT-C, RAPI and WEMWBS was assessed using Spearman's correlation coefficients and is shown in *Table 4* and *Figure 8*. Unsurprisingly, there was a strong correlation between AUDIT and AUDIT-C scores. The RAPI score showed a moderate association with both AUDIT and AUDIT-C score: this is illustrated in *Figure 8*. However, the WEMWBS score showed very weak correlations with all of the other measures.

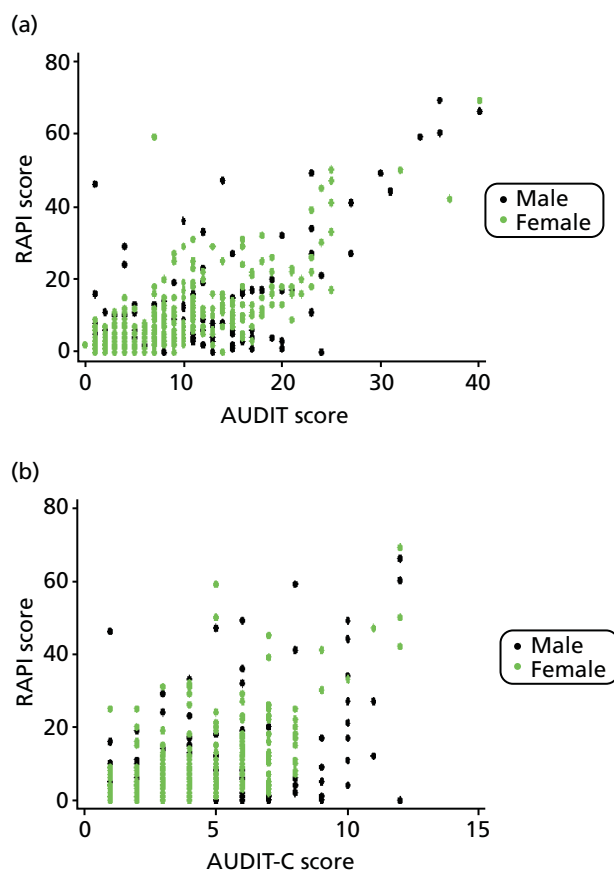


FIGURE 8 Associations between AUDIT and AUDIT-C and RAPI.

TABLE 4 Correlations between AUDIT, AUDIT-C, RAPI and WEMWBS

	AUDIT	AUDIT-C	RAPI
AUDIT-C	0.96		
RAPI	0.76	0.65	
WEMWBS	-0.13	-0.08	-0.22

Results of comparison of surveys at different time points

The distributions of the numeric variables across the three time points were summarised in *Table 1*. There appeared to be a slight shift upwards in some variables, as seen in changes to medians or quartiles. However, the distributions of AUDIT, AUDIT-C, RAPI and WEMWBS scores were formally compared across the three time points using the Kruskal–Wallis test. There was no significant difference between RAPI scores and WEMWBS scores over time ($p > 0.05$). However, there were significant differences over time for both AUDIT and AUDIT-C scores, with both following the same pattern when data at pairs of time points were compared using Mann–Whitney *U*-tests. The median AUDIT scores were '2', '4' and '4' at the three time points, and the consecutive median AUDIT-C scores were '2', '3' and '3'. The differences between TP1 and TP2 were statistically significant; however, there were no significant differences between TP2 and TP3. These results show a small shift upwards in the distributions of AUDIT and AUDIT-C over the 12-month period. UK guidelines recommend at least 1 hour per day of exercise for young people aged 5 to 25 years.¹⁶⁷ The median number of days in the previous week in the present study in which there was at least an hour of physical activity was four days at TP1 and TP2, and three days at TP3. The median number of days including physical exercise that were reported in a typical week was four days at all time points. The recommended daily intake of fruit and vegetables per day is five (www.nhs.uk/Livewell/5ADAY/Pages/5ADAYhome.aspx). The median number of daily portions of fruit consumed by young people in the present study was two at all time points, and the median daily portions of vegetables was also two at all time points.

The distributions of the categorical variables across the three time points were summarised in *Table 3*. For the alcohol-related categorical variables reported in *Table 3a*, the percentage of participants scoring '2' or above (the cut-off suggested for adolescents) increased from 58% at TP1 to 66% (TP2) and 69% at TP3. The percentage of participants who scored ≥ 8 (the adult cut-off) was 26% at TP1, 29% at TP2 and 32% at TP3. For AUDIT-C, 21% of participants scored ≥ 5 (the adult cut-off) at TP1, 29% at TP2 and 32.6% at TP3.

The distribution of alcohol frequency categories measured by the A-SAQ appears to have shifted slightly upwards over time. Thirty-nine per cent of participants reported drinking at least four times but not every month (i.e. scored positive) with 47% at TP2 and TP3. As A-SAQ is an ordered categorical variable, the distribution over time was also compared using Kruskal–Wallis and Mann–Whitney tests. As with the pattern seen in AUDIT and AUDIT-C, the differences between TP1 and TP2 were statistically significant, as were the differences between TP1 and TP3; however, there were no significant differences between TP2 and TP3.

There was a slight decline in the number of young people who had never had sex over time and there was an increase over time of young people regretting sex after consuming alcohol and having sex without using a condom after consuming alcohol.

For the non-alcohol-related categorical variables reported in *Table 3b*, there was a slight increase in the number of smokers over the year. The majority of young people spent their free time going out with friends, although this reduced from 61% and 62% at TP1 and TP2, respectively, to 54% at TP3. After this, the next most popular answer was to spend time with friends in their own home or their friends' homes. Spending time with brothers and sisters or with family were the least popular options.

Comparison of named and anonymous participants

The percentage of participants leaving their name on the TP1 questionnaire varied considerably between schools, from as few as 37% up to 74%. The percentage of participants who left their names and scored positive on the A-SAQ varied from 11% to 34% across schools (as a percentage of the total participants completing the survey). A further 21.3% of participants scored positive on the A-SAQ but did not leave their names, so were potentially eligible but not willing to participate. Combining results across the participating schools, the mean AUDIT score of those young people who left their names was lower than those who did not. Using a Mann–Whitney *U*-test on combined data across schools, there was a statistically significant difference between the distributions of AUDIT scores in those young people who did and did not ($p = 0.0002$), with a tendency towards higher scores in those who did not leave their name (means of 5.7 vs. 4.4). The results are summarised in *Table 5*.

Missing data within measures

Table 6 shows a breakdown of missing data for the items making up a questionnaire score. When an item was missing from a measure, an overall score was not computed for that measure. With the exception of the second item on the AUDIT scale, there seems little sign that items are problematic in terms of being missing more often. For the AUDIT score, the second item had a high number of missing values, because there was no tick box for young people who do not drink. This was accounted for when calculating the overall AUDIT score by automatically giving these young people an AUDIT score of '0' if they had responded that they had not drunk alcohol in the last 6 months using the first question in the AUDIT scale (the lowest category). For the other AUDIT questions, missing data values ranged from 0.3% to 3.5%. There were slightly more missing data for RAPI questions, with the percentage of missing values ranging from 1.4% to 4.6%. WEMWBS has the most missing data of all of the measures, ranging from 2.8% to 9%. Overall, there were fewer missing data at TP3 and the most missing data at TP2. The response rate to the whole survey was lower at TP3, so the lower percentage missing on individual items at TP3 may reflect the fact that pupils present on the day of the survey were more likely to complete more items.

TABLE 5 Comparison of percentages of pupils leaving names by school

School	No. of participants completing survey at TP1	% participants leaving name	% participants scoring positive on A-SAQ and leaving name	% participants scoring positive on A-SAQ and not leaving name	Mean AUDIT score of participants who left name	Mean AUDIT score of participants who did not leave name
A	167	72.5	23.3	13.2	3.9	6.8
B	115	52.2	20.9	18.3	4.5	5.5
C	81	74.1	34.6	14.8	6.7	9.9
D	307	36.5	11.1	24.8	3.6	4.8
E	240	47.5	16.3	27.1	4.1	6.7
F	215	39.5	13.5	22.8	4.8	5.2
G	155	50.3	20.0	18.1	4.5	5.4
Total	1280	49.2	17.5	21.3	4.4	5.7

TABLE 6 Summary of missing data for AUDIT, RAPI and WEMWBS by individual items (TP1, TP2 and TP3)

Measure	Question	% missing		
		TP1 (n = 1280)	TP2 (n = 1256)	TP3 (n = 1161)
AUDIT	How often do you have a drink containing alcohol?	1.3	1.8	0.5
	How many standard drinks containing alcohol do you drink on a typical day when you are drinking?	21.1	17.4	2.0
	How often have you had six or more standard drinks if female, or eight or more if male, on a single occasion in the last 6 months?	3.5	3.4	1.3
	How often during the last 6 months have you found that you were not able to stop drinking once you had started?	1.2	2.5	0.3
	How often in the last 6 months have you failed to do what was normally expected of you because of your drinking?	1.5	2.8	0.5
	How often in the last 6 months have you needed an alcoholic drink in the morning to get you going?	1.0	2.5	0.5
	How often in the last 6 months have you had a feeling of guilt or regret after drinking?	1.3	2.9	0.7
	How often in the last 6 months have you not been able to remember what happened when drinking the night before?	1.6	2.9	0.6
	Have you or someone else been injured as a result of your drinking?	1.6	3.3	0.9
	Has a relative/friend/doctor/health worker been concerned about your drinking or advised you to cut down?	2.0	3.1	0.8
RAPI (how many times in the last 6 months)	Not able to do your homework or study for a test	2.2	3.7	1.4
	Got into fights with other people	1.8	3.7	1.4
	Missed out on other things because you spent too much money on alcohol	1.9	3.9	1.5
	Went to work or school high or drunk	2.2	3.7	1.5
	Caused shame or embarrassment to someone	2.2	3.9	1.8
	Neglected your responsibilities	2.3	4.3	1.6
	Relatives avoided you	2.1	4.1	1.6
	Felt you needed more alcohol than you used to in order to get the same effect	2.0	3.8	1.6
	Tried to control your drinking	2.3	4.2	2.0
	Had withdrawal symptoms	2.3	4.0	1.7
	Noticed a change in your personality	2.3	4.2	1.7
	Felt you had a problem with alcohol	2.4	4.6	1.8
	Missed a day (or part of a day) of school or work	2.5	4.1	1.8
	Wanted to stop drinking but could not	2.3	4.3	2.0
	Suddenly found yourself in a place that you could not remember getting to	2.5	4.3	1.7
	Passed out or fainted suddenly	2.7	4.1	2.0

continued

TABLE 6 Summary of missing data for AUDIT, RAPI and WEMWBS by individual items (TP1, TP2 and TP3) (*continued*)

Measure	Question	% missing		
		TP1 (n = 1280)	TP2 (n = 1256)	TP3 (n = 1161)
WEMWBS (how often)	Had a fight, argument or bad feeling with a friend	3.0	4.4	1.9
	Had a fight, argument or bad feeling with a family member	3.2	4.5	1.8
	Kept drinking when you promised yourself not to	3.0	4.3	2.0
	Felt you were going crazy	3.0	4.4	2.0
	Had a bad time	2.9	4.3	1.9
	Felt physically or psychologically dependent on alcohol	3.0	4.2	1.7
	Was told by a friend, neighbour or relative to stop or cut down drinking	2.9	4.2	1.8
	I've been feeling optimistic about the future	5.9	8.3	2.8
	I've been feeling useful	5.6	8.6	3.2
	I've been feeling relaxed	5.9	8.7	3.7
	I've been feeling interested in other people	6.3	9.0	3.5
	I've had energy to spare	5.8	8.5	3.1
	I've been dealing with problems well	5.7	8.3	3.2
	I've been thinking clearly	6.0	8.6	3.4
	I've been feeling good about myself	5.8	8.2	3.4
	I've been feeling close to other people	6.3	8.3	3.8
	I've been feeling confident	5.7	8.4	3.5
	I've been able to make up my own mind about things	5.6	8.5	3.6
	I've been feeling loved	6.2	8.9	3.8
	I've been interested in new things	5.8	8.4	3.4
	I've been feeling cheerful	5.5	8.4	3.3

Summary

The survey response rates among pupils whose parents allowed them to take part were 92% at baseline (TP1), 90% at 6 months (TP2) and 84% at 12 months (TP3). Levels of missing data were low for all variables. The highest rate of missing data was seen for WEMWBS, which was the last set of questions in the survey pack. A comparison of the distributions of AUDIT and AUDIT-C scores between subgroups at TP1 demonstrated that gender, smoking and sexual behaviour were significantly associated with young people's current drinking behaviour. The comparisons of scores over three time points suggests that there was little or no change in measures of alcohol use, alcohol-related problems and well-being within this age group over the course of a year, except for small but statistically significant shifts upwards in the distributions of AUDIT, AUDIT-C and A-SAQ between the first and second surveys. In every school, mean AUDIT scores were higher for young people who did not leave their names on the questionnaire than for those who did.

Chapter 5 External pilot trial

Key points for Chapter 5

- Seven schools were randomised to the three trial arms – control ($n = \text{two}$), intervention 1 ($n = \text{two}$), intervention 2 ($n = \text{three}$) – and retained at 12-month follow-up.
- Sixteen per cent of young people who completed the survey at TP1 met eligibility criteria for the trial; 80% of those eligible were recruited into the trial.
- Eighty per cent of those recruited into the trial completed the 12-month follow-up.
- Of the 75 young people recruited to intervention 2, only eight (10%) received both the individual and family-centred interventions: the remainder received only the individual-level intervention (intervention 1).
- There were very low levels of missing data at both baseline and 12-month follow-up.
- The TLFB was completed with all young people who attended at 12-month follow-up. There was some evidence that results on AUDIT, AUDIT-C and A-SAQ scales showed a slight shift to less alcohol consumption or risk behaviours at 12 months compared with baseline.

The external pilot trial was a parallel-group, three-arm cRCT with randomisation at the level of schools. A cluster randomised design was chosen to reduce the potential for bias due to contamination between young people allocated to different arms within the same school. The three arms were control, intervention 1 and intervention 2 (details of interventions are given in *Chapter 3*). The primary aim of the pilot trial was to assess feasibility and acceptability to plan a future definitive trial, including estimating rates of eligibility, consent, participation and retention at 12 months.

Process and measures: baseline

The questionnaire distributed at TP1 provided young people with the opportunity to volunteer their contact information or to complete the questionnaire anonymously. This TP1 questionnaire facilitated screening for the trial, and young people who screened positive for risky alcohol use using the A-SAQ and who provided their name at TP1 were invited to attend an appointment with a learning mentor to assess eligibility and provide consent. Young people were excluded from participation if they were already seeking help for an alcohol use disorder (AUD), receiving support from child and adolescent mental health services or had not been given consent by parents to take part.

Process and measures: 12-month follow-up

Twelve-month follow-up appointments with trial participants took place when young people had begun the next school year (Year 11). Collection of follow-up data began in January 2013 and was completed in April 2013. Trial participants who had moved schools during this time and were unable to be contacted for this appointment were lost to the trial. No trial participants had language or literacy problems that required additional support with reading the documentation. The session involved completion of three separate questionnaires: A-SAQ, AUDIT and 28-day TLFB, chosen to measure different aspects of drinking behaviour and anticipated to be primary or secondary outcome measures in a future definitive trial. All three measures were completed during a single one-to-one appointment with a learning mentor, which took place during school time. The order of presentation of A-SAQ and AUDIT were randomised and completed by the young person alone, with the TLFB being the last tool completed with the learning mentor. Wherever possible, the same learning mentor conducted both intervention and follow-up sessions. However, owing to staffing changes at participating schools, on some occasions a different learning mentor conducted the follow-up

appointment. If this learning mentor was a newly recruited member of school staff then he/she was provided with a condensed training session, focusing on the intervention delivery phase of the study, in addition to training in how to deliver the 12-month follow-up appointment. The planned primary outcome for a future definitive trial is the 28-day TLFB questionnaire, completed by trial participants at 12-month follow-up. The TLFB has been validated for use in this population^{168–170} and involves a retrospective interview administered by the learning mentor to ascertain actual alcohol consumed over the 28-day period prior to the interview. Four alcohol consumption measures were derived from the 28-day TLFB: total alcohol units consumed in a 28-day period, percentage of days abstinent, mean number of drinks per drinking day, and number of days on which alcohol consumption was more than two units. The questionnaire invites participants to recall their daily alcohol consumption over the 28-day period and can examine total alcohol consumption as well as patterns of alcohol consumption (see *Appendix 3*). It is important that sufficient information is recorded to calculate accurately the units of alcohol consumed, including the type (and brand) of alcohol and the volume (or size of container) of alcohol consumed. To facilitate collection of data, learning mentors were provided with prepared copies of the 28-day TLFB questionnaire. Tools were marked with dates (such as Christmas, examination periods and local football games) in order to provide prompts and aid form completion. Other memorable dates specific to the young person were identified and used to aid recollection.

Design

Pilot trial sample size

As this was a pilot trial, a formal power calculation was not required. However, providing data to design a future definitive trial is an important function of a pilot study. A minimum number of 30 participants per intervention group at follow-up has been recommended to estimate key parameters for this purpose.¹⁷¹ We used data from previous studies to estimate the proportions of young people who would be eligible, consent to enter the study and provide data at 12-month follow-up.^{97,127} Our estimates suggest that the minimum number of 30 per arm providing follow-up data would be achieved if all pupils in Year 10 across seven schools were invited to take part (*Figure 9*). Note that we estimated that recruitment would be much lower for the intervention 2 arm, so two schools were randomised to each of the control and intervention 1 arms, but three schools were randomised to the intervention 2 arm.

Pilot trial outcomes

- Percentage of those who did not meet exclusion criteria, completed the TP1 survey and were positive on A-SAQ, and provided their name and contact details (% eligible).
- Percentage of eligible young people who were recruited to trial (% recruited).
- Percentage of those recruited who provided data at 12-month follow-up (% retained).

A key aim of the feasibility study was to investigate whether the primary and secondary outcomes and baseline characteristics in a definitive trial could be measured on all participants.

Methods

Randomisation

Schools agreed to take part in the study prior to randomisation, and were subsequently informed of their allocated intervention. Allocation to trial arm was conducted by the study statistician with randomisation at the school level. The study catchment area enabled broad population coverage and the randomisation achieved balance on two school-level variables (numbers of pupils in school year and proportion receiving free school meals) (*Table 7*). Neither school staff and pupils nor researchers were blind to the intervention allocated.

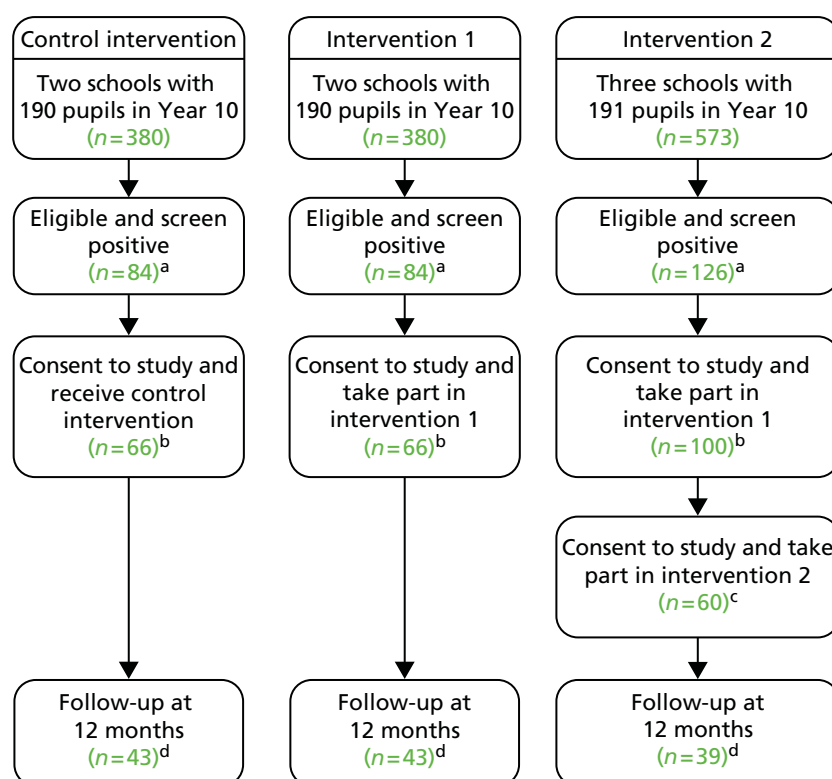


FIGURE 9 Estimates of eligibility, recruitment and retention used to plan the sample size of the pilot trial. The estimates are based on previous studies: a, 22% follow-up;¹²⁷ b, 79% follow-up;¹²⁶ c, 88% conservative estimate of take-up rate taken from Walton *et al.*⁹⁷ and Conrod *et al.*;¹²⁷ d, 65% follow-up rate.¹⁷²

TABLE 7 Randomisation and allocation to trial arm

School site and study condition	No. of pupils in Year 10	% of free school meals
School F (control)	250	12
School G (control)	176	6
School E (intervention 1)	268	8
School A (intervention 1)	194	15
School C (intervention 2)	98	33
School B (intervention 2)	138	13
School D (intervention 2)	351	2

It is common in cRCTs that participants are not blind to the intervention they receive.¹⁷³ In this pilot trial, schools were not aware of to which trial arm they had been assigned at the time they agreed to take part. In addition, the pupils were screened before the random allocation of their school to trial arms was known. They were told that they might be chosen to receive advice on their drinking in one of three ways, and were not aware of which this might be at the time they were invited to take part in the study. This approach should have avoided any potential bias at the recruitment stage.¹⁷⁴

It was necessary for the learning mentors to be aware of the trial allocation. There is potential for 'resentful demoralisation' of those delivering the intervention if they have not been allocated to the trial arm that they prefer.¹⁷⁵ However, in this study, the head teachers and learning mentors were very keen to receive any training about dealing with alcohol issues (and those in all arms received general advice) and there did not appear to be any disappointment with the allocations.

Statistical analysis

The eligibility, recruitment and retention rates for the schools and young people have been summarised in a Consolidated Standards of Reporting Trials (CONSORT) diagram (*Figure 10*). The data collected for trial participants at TP1 and TP3 were summarised with descriptive statistics by trial arm, and combined across trial arms. This was to investigate suitability of scales and variables for a future definitive study, to establish baseline characteristics, and to summarise the outcomes. The percentage of missing and implausible values was reported for all variables, along with either a five-number summary (minimum, lower quartile, median, upper quartile, maximum) for numeric variables, or numbers and percentages in each category for categorical variables. In addition, at TP3, the variables derived from the 28-day TLFB and the AUDIT and AUDIT-C measures were summarised by their mean and standard deviation (SD): these were used to inform a sample size calculation for a definitive trial, and the comparison of mean and median values allowed consideration of the shape of each distribution. All analyses used the intention-to-treat populations.

Results

Recruitment and retention

Eleven schools were assessed as eligible to participate in the trial (*Figure 10*). Four of the eleven schools did not respond to our contact/declined to participate, and seven schools agreed to meet with the research team to discuss the project. One school said no to participating in the study, based on current workload and staff commitments. Three schools did not return telephone and e-mail messages. Once the required number of schools were recruited (seven) the research team did not continue to contact the three schools from which we had received no response. All schools who met with a researcher subsequently agreed to take part in the study. Therefore seven schools were randomised to the three trial arms – two to the control arm, two to intervention 1 and three to intervention 2. There were 1475 young people aged 14 and 15 years in Year 10 across the seven schools. Of those, 195 (13.2%) were either opted out by parents or not at school when the survey took place. A further 1051 (71.3%) scored negative on the A-SAQ (783, 53.1%). Of the total, 498 scored positive on the A-SAQ (38.9%). There were 268 who scored positive but did not leave their names (268, 18.2%). This left 229 young people (15.5% of combined year groups) who were potentially eligible for the trial and were referred to a learning mentor to discuss their possible enrolment in the trial. This number was lower than expected (i.e. 22%), probably because not all young people left their names, to allow them to be contacted about the trial. At this stage, a further 47 young people were not recruited to the pilot trial for a number of reasons including repeatedly not turning up for their appointment with the learning mentor (8, 3.5%), not consenting (23, 10.0%), moving school (4, 1.7%) or behavioural issues (10, 4.4%). This left 182 (79.5% who were eligible) young people who were recruited to the trial. This recruitment rate is close to that expected when planning the study. There were 53 in the Control arm, 54 in the Intervention 1 arm who received Intervention 1 and 75 in Intervention 2 arm.

All young people allocated to the control and intervention 1 arms received their intervention as planned. In the intervention 2 arm, all 75 received intervention 1 but 57 young people and/or their families did not consent to the family meeting (intervention 2), and a family meeting could not be arranged for a further 10, leaving just eight young people who received both Interventions 1 and 2 (10.7% of those allocated to the intervention 2 arm) (see *Figure 10*).

Across all arms, eight young people did not consent to follow-up at 12 months (TP3). In addition, seven were repeatedly absent at follow up, three had moved school, three had behavioural issues and one was withdrawn by the school. This meant that 160 (88%) young people completed the 12-month follow-up: 44 (83%) in the control arm, 49 (90.1%) in intervention 1 and 67 (89.3%) in intervention 2. These retention rates were higher than those that were expected when planning the trial. So, overall, of the initial 1475 young people approached, 15.5% were eligible for the trial (14.2% of self-reported drinkers); 79.5% of the 229 eligible young people were recruited; and 88% of the 182 recruited provided follow-up data.

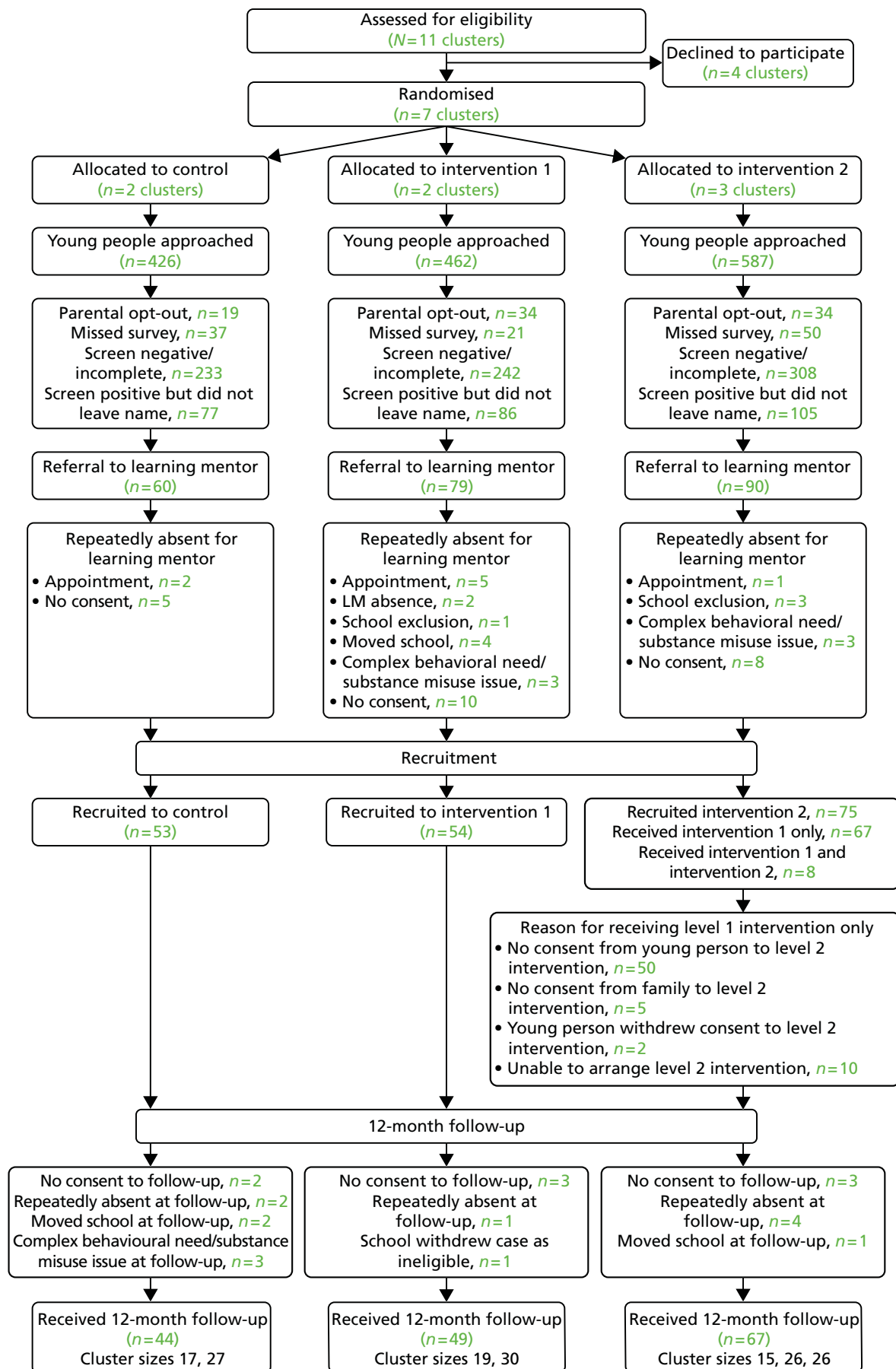


FIGURE 10 Trial CONSORT diagram. LM, learning mentor.

Characteristics of trial participants at baseline (time point 1)

Categorical data

The categorical baseline characteristics for the trial participants are summarised in *Table 8*.

Gender was not evenly distributed across the trial groups. The intervention 1 arm comprised 37% males, with control and intervention 2 having 43% and 51% males, respectively. Ethnic group was fairly evenly distributed, with very few non-white participants in each arm, reflecting the ethnic mix of the local authority.¹⁷⁵

The eligibility criterion for the trial was a minimum A-SAQ score (reporting drinking more than three units at least four or more times in the last 6 months), so at TP1 all reported at least this frequency. There are similar percentages of participants across the trial arms reporting consumption in the three highest categories possible at this time point. Just one participant in the intervention 1 arm reported daily drinking.

TABLE 8 Summary of categorical baseline (TP1) characteristics by trial arm and combined across arms

Variable	TP1 baseline data: distribution over categories ^a by trial arm (%)			
	Control, n = 53	Intervention 1, n = 54	Intervention 2, n = 75	Overall, n = 182
Gender				
Missing	0	0	0	0
Male	43.4	37.0	50.7	44.5
Ethnic group				
Missing (%)	0	1 (1.9)	0	1 (0.5)
White	96.2	100.0	98.7	98.3
A-SAQ (per last 6 months)				
Missing	0	0	0	0
Four or more times but not every month	34.0	31.5	29.3	31.3
Once or more per month but not every week	30.2	35.2	37.3	34.6
Every week but not every day	35.9	31.5	33.3	33.5
Every day	0	1.9	0	0.6
Sex regretted after alcohol				
Missing (%)	0	0	4 (5.3)	4 (2.2)
Never had sex at all	58.5	42.6	47.9	49.4
Yes	15.1	22.2	22.5	20.2
No	26.4	35.2	29.6	30.3
Sex without condom after alcohol				
Missing (%)	0	0	4 (5.3)	4 (2.2)
Never had sex at all	58.5	42.6	49.3	50.0
Yes	13.2	20.4	18.3	17.4
No	28.3	37.0	32.4	32.6
Smoker				
Missing (%)	1 (1.9)	1 (1.9)	4 (5.3)	6 (3.3)
Yes	44.2	35.9	40.9	40.3

TABLE 8 Summary of categorical baseline (TP1) characteristics by trial arm and combined across arms (*continued*)

Variable	TP1 baseline data: distribution over categories ^a by trial arm (%)			
	Control, n = 53	Intervention 1, n = 54	Intervention 2, n = 75	Overall, n = 182
Age when first smoked				
Missing (%)	0	1 (1.9)	1 (1.3)	2 (1.1)
Never smoked	34.0	37.7	33.8	35.0
≤ 8 years	0.0	1.9	4.1	2.2
9–10 years	5.7	1.9	8.1	5.6
11–12 years	30.2	28.3	21.6	26.1
13–14 years	28.3	26.4	29.7	28.3
> 14 years	1.9	3.8	2.7	2.8
Use of free time^b				
With friends at your house or theirs	32.1	33.3	48.0	39.0
Go out somewhere with friends	79.2	66.7	72.0	73.1
Spend time with your family	11.3	7.4	13.3	11.0
Spend time with siblings	1.9	0.0	8.0	3.8
Spend time by yourself	17.0	18.5	18.7	17.6

^a Percentages calculated across possible categories of each variable, excluding the missing category.
^b There are no missing data for 'Use of free time', as these were tick-box questions – participants could tick multiple boxes or none.

Overall, 40% of participants reported that they were smokers, although the intervention 1 arm had a slightly lower percentage than the other two groups (36%). This compares with 29% of young people aged 14 years and 45% aged 15 years in the general population.⁴ The age when participants first smoked was fairly evenly distributed across the three trial arms. Few began smoking before the age of 10 years, with a majority of current smokers beginning to smoke between the ages of 11 and 14 years. Forty-nine per cent of participants said they had never had sex (control, 59%; intervention 1, 43%; intervention 2 48%). Of those who had engaged in sex, 40% had regretted sex after drinking alcohol and 35% had sex without a condom after drinking alcohol. There were slightly fewer young people answering 'yes' to those questions in the control arm than in the other two arms.

The use of free time questions seemed to be similarly distributed across the trial arms. The most popular way to spend free time was going out with friends, with 73% of participants ticking this box. The next most popular use of free time was meeting friends at the friend's or the participant's home, with 39% of participants responding positively. However, there were substantially more answering positively in the intervention 2 group (48%). Spending time with brothers and sisters, with family or on their own were the least popular options (3.8%, 11% and 17.6% respectively).

We looked to see whether there were any problems with either missing data or implausible values for some scales, to help decide which variables should be included in a future trial. Missing values for the categorical baseline characteristics (see *Table 9*) were very low, with the maximum being four respondents to the questions about smoking status and sex in the intervention 2 arm. No missing values were recorded for the questions about free time, as these were tick-box questions for positive answers. However, there was one (1.0%) young person in the control arm, two (3.7%) young people in the intervention 1 group and two (2.7%) young people in the intervention 2 group who did not tick any boxes about the way they

TABLE 9 Summary of numeric baseline variables by trial arm and combined across arms

TP1: baseline data for trial participants										
Measure (potential scale range)	Variable by trial arm	N	Missing (%)	Implausible values (%) ^a	n available	Minimum	Lower quartile	Median	Upper quartile	Maximum
AUDIT (0–40)	Control	53	5.7	–	50	1	3	8	13	25
	Intervention 1	54	1.9	–	53	1	5	9	13	36
	Intervention 2	75	6.7	–	70	0	4	8	13	31
	Overall	182	4.9	–	173	0	4	8	13	36
AUDIT-C (0–12)	Control	53	5.7	–	50	1	2	4	6	10
	Intervention 1	54	1.9	–	53	1	3	5	6	12
	Intervention 2	75	6.7	–	70	0	3	4	6	10
	Overall	182	4.9	–	173	0	3	4	6	12
RAPI (0–69)	Control	53	0.0	–	53	0	0	5	12	59
	Intervention 1	54	1.9	–	53	0	3	7	12	60
	Intervention 2	75	8.0	–	69	0	1	5	12	49
	Overall	182	3.8	–	175	0	2	6	12	60
WEMWBS (14–70)	Control	53	3.8	–	51	18	40	45	53	64
	Intervention 1	54	5.6	–	51	14	39	45	54	69
	Intervention 2	75	18.7	–	61	23	44	47	55	70
	Overall	182	10.4	–	163	14	39	46	54	70
Physical activity last week – days (0–7)	Control	53	7.5	7.5	45	0	2	4	5	7
	Intervention 1	54	7.4	7.4	46	0	2	4	5	7
	Intervention 2	75	9.3	8.0	62	0	3	4	6	7
	Overall	182	8.2	7.7	153	0	2	4	5	7

TP1: baseline data for trial participants										
Measure (potential scale range)	Variable by trial arm	N	Missing (%)	Implausible values (%) ^a	n available	Minimum	Lower quartile	Median	Upper quartile	Maximum
Physical activity typical week days (0–7)	Control	53	3.8	7.5	47	0	2	4	5	7
	Intervention 1	54	7.4	5.5	47	0	2	4	5	7
	Intervention 2	75	6.7	12.0	61	0	2	4	5	7
	Overall	182	6.0	8.8	155	0	2	4	5	7
No. of pieces of fruit on a typical day (0–14)	Control	53	1.9	0.0	52	0	1	2	3	6
	Intervention 1	54	0.0	0.0	54	0	1	2	2	10
	Intervention 2	75	1.3	0.0	74	0	1	2.5	3	10
	Overall	182	1.1	0.0	180	0	1	2	3	10
Portions of vegetables on a typical day (0–22)	Control	53	3.8	0.0	51	0	1	2	3	6
	Intervention 1	54	1.9	0.0	53	0	1	2	3	7
	Intervention 2	75	6.7	0.0	70	0	1	2	3	10
	Overall	182	4.4	0.0	175	0	1	2	3	10
a Implausible values were those that were impossible (> 7 days of physical activity in a week) or seemed to be unlikely or more extreme than the answers the majority of young people had given (> 14 portions of fruit and > 22 portions of vegetables).										

^a Implausible values were those that were impossible (> 7 days of physical activity in a week) or seemed to be unlikely or more extreme than the answers the majority of young people had given (> 14 portions of fruit and > 22 portions of vegetables).

spent their free time, which may indicate that none of these activities was one in which they took part and also that they did not answer these questions.

Numeric data

The distribution of numeric baseline (TP1) variables for the trial participants is summarised in *Table 9*.

The AUDIT scores were similarly distributed across the trial arms, with median scores per arm of 8 to 9. There was a wide range of scores reported. AUDIT-C scores were similarly distributed across the trial arms, with median scores of 4 or 5, and a wide range of scores reported. The RAPI score measured alcohol problems, with higher scores indicating more risky drinking. Median scores were comparatively low and similar between trial arms (medians of 5 or 7).

The WEMWBS scale assessed general psychological health, with higher scores indicating greater well-being. Extremes at both ends of the scale were occasionally reported. Typical values were similarly distributed across the trial arms, with median scores of 45 or 47.

For the measures of physical activity and daily consumption of portions of fruit and vegetables there was little difference between distributions across the trial arms. The median numbers of days on which participants exercised in the last or a typical week was two. Fruit and vegetable consumption was low, with two being the median number of items consumed on a typical day.

We looked to see whether there were any problems with either missing data or implausible values for some scales to help decide which variables should be included in a future trial. For AUDIT and AUDIT-C there were three missing values in the control group, one in the intervention 1 arm and five in the intervention 2 arm. For the RAPI, there were no missing scores in the control group, one missing score in intervention 1, and six missing scores in intervention 2. For WEMWBS, the numbers of missing scores were two, three and 14, respectively, across the arms. For the measures of physical activity and the amount of fruit and vegetables consumed, up to seven young people failed to answer. There were no implausible values for portions of fruit and vegetables consumed, but for the measures of physical activity there were between four and nine implausible values in each arm (reporting activity on > 7 days per week).

Results of outcome measures at 12-month follow-up (time point 3)

The four outcome measures derived from 28-day TLFB plus the results of A-SAQ, AUDIT and AUDIT-C collected at 12-month follow-up (TP3) are reported in *Table 10*. The five-number summaries show that there is a lot of variation within the groups. Across all the trial participants the range for the units of alcohol consumed in the 28-day period was 0–235 units, with a median of 10.3, a mean of 22.7, and a large SD of 36.3. There were occasional participants who reported consuming very high total amounts of alcohol; however, staff were trained in how to use the TLFB to maximise the validity of the answers. Typical levels are less well balanced between trial arms, with median levels of around eight in the control and intervention 2 arm and 14 in the intervention 1 arm.

Percentage days abstinent (from TLFB) had similar distributions across the trial arms (median per arm = 93%), as did days consuming more than two units (median per arm = 1 or 2). For drinks per drinking day, there was also some variability between the trial arms (medians 7.8, 7.6 and 5.8). Note that this variable cannot be calculated for those participants who do not consume any alcohol in the 28-day period.

There was a wide range observed in AUDIT scores at TP3 (0–28), but little variation between trial arms (medians 5–6). A similar pattern was seen in AUDIT-C scores, for which the trial arm median scores were '4–5'. For AUDIT and AUDIT-C we have data at TP1 and TP3. The median AUDIT score across all arms was

TABLE 10 Summary of outcome measures at TP3 for trial participants by trial arm and combined across arms

TP3: 12-month follow-up trial outcomes										
Measure (potential scale range)	Trial arm	N	Missing (%)	Minimum	Lower quartile	Medium	Upper quartile	Maximum	Mean	SD
Units of alcohol consumed in 28-day period	Control	44	0	0	0.8	8.4	31.8	234.7	27.6	47.9
	Intervention 1	49	0	0	1.3	14.1	33.6	93.4	22.6	25.4
	Intervention 2	67	8 (11.9)	0	0	8	21.4	189.9	19.1	34.1
	Overall	160	8 (5.0)	0	0.7	10.3	30.0	234.7	22.7	36.3
Percentage days' abstinence	Control	44	0	68	86	93	96	100	90.8	8.7
	Intervention 1	49	0	75	86	93	96	100	91.5	6.8
	Intervention 2	67	4 (6.0)	50	86	93	100	100	91.2	10.4
	Overall	160	4 (2.5)	50	86	93	96	100	91.2	8.8
Drinks per drinking day	Control	44	10 (22.7)	0.5	3.1	7.8	12.2	28.3	9.3	8.1
	Intervention 1	49	8 (16.3)	0.6	2.9	7.6	11.7	21.3	8.1	5.7
	Intervention 2	67	26 (38.8)	0.8	4	5.6	10.7	28	7.9	6.2
	Overall	160	44 (27.5)	0.5	3.3	7.3	11.0	28.3	8.4	6.6
Days, more than two units	Control	44	0	0	0	1	3	9	2.1	2.3
	Intervention 1	49	0	0	0	2	3	6	1.9	1.9
	Intervention 2	67	8 (11.9)	0	0	1	3	14	1.8	2.4
	Overall	160	8 (5.0)	0	0	1	3	14	1.9	2.2
										continued

continued

TABLE 10 Summary of outcome measures at TP3 for trial participants by trial arm and combined across arms (continued)

TP3: 12-month follow-up trial outcomes											
Measure (potential scale range)	Trial arm	N	Missing (%)	Minimum	Lower quartile	Medium	Upper quartile	Maximum	Mean	SD	
AUDIT (0–40)	Control	44	0	0	3	6	10	28	7.1	5.6	
	Intervention 1	49	0	0	4	6	11	24	7.5	5.6	
	Intervention 2	67	4 (6.0)	0	3	5	9	21	6.1	4.4	
	Overall	160	4 (2.5)	0	3	5	9.5	28	6.8	5.2	
AUDIT-C (0–12)	Control	44	0	0	3	4	6	10	4.4	2.4	
	Intervention 1	49	0	0	3	5	6	9	4.4	2.4	
	Intervention 2	67	1 (1.5)	0	2	4	5	9	3.9	2.0	
	Overall	160	1 (0.6)	0	3	4	6	10	4.2	2.2	
A-SAQ	Distribution across categories (%): frequency in last 6 months										
				Never	Fewer than four times	Four or more times but not every month	More than once per month but not every week	Every week but not every day			Every day
	Control	44	1 (2.3)	6.9	18.6	25.6	32.6	16.3	0	0	
	Intervention 1	49	0	8.2	14.3	32.7	28.6	16.3	0	0	
	Intervention 2	67	0	6.0	28.4	26.9	23.9	14.9	0	0	
Overall	160	1 (0.6)	6.9	21.4	28.3	27.7	15.7	0	0		

lower at TP3 ('5') than at TP1 ('8'), although there is no change in medians for AUDIT-C ('4') between TP1 and TP3. No formal comparisons were carried out, so any changes must be interpreted with caution. Some young people were lost to follow-up because of complex behavioural problems, repeated absence, moving school, or deciding that they no longer wished to participate in the trial. The median AUDIT score at TP1 of the 22 participants who dropped out by TP3 was '14.5' and their median AUDIT-C score was '5.5'. Given some of the reasons for loss to follow-up, it is perhaps not surprising that typical AUDIT scores for young people retained at TP3 were lower than at baseline for all of those entering the trial. However, when only those participants who provided AUDIT scores at both TP1 and TP3 are included in the analysis, there does appear to be a slight tendency towards a reduction in AUDIT scores (although this was not seen for AUDIT-C scores). This is illustrated in *Figure 11* where the distribution of individual changes in AUDIT scores is shown across trial arms. There was considerable variation in the change scores (AUDIT score at TP1 – AUDIT score at TP3) indicating both increases and decreases over the year. However, although the median change is zero for the control and intervention 2 trial arms, it can be seen that, in all arms, the positive changes (indicating lower AUDIT score at TP3) tend to be larger than the negative ones. However, any difference between trial arms must be interpreted with caution, as they are based on data from only two or three clusters.

We also had the distribution of the A-SAQ question available at TP1 and TP3. The summary statistics in *Table 10* show that the distribution was shifted towards less frequent consumption at TP3 than at TP1. All had reported drinking four or more times in the last 6 months at TP1, but by TP3, 28% across all arms reported less frequent drinking than this. The percentage of young people reporting drinking every week had also approximately halved in all arms.

The reduction in alcohol use over 12 months in the AUDIT and A-SAQ measure was observed in all trial arms. This may have reflected a general change in drinking behaviour or socially desirable responses due to taking part in the trial, rather than a response to a particular intervention.

At TP3, levels of missing data were very low. For the TLFB measures (units of alcohol consumed in a 28-day period, percentage of days when abstinent, and days consuming more than two units), only the intervention 2 arm had any missing data. This amounted to 12% of missing data for units of alcohol consumed and days consuming more than two units, and 6% for percentage days abstinent. The higher numbers of missing values for drinks per drinking day is due to some of the young people not drinking at all during the 28-day period, and therefore not having a value for this. This applied to 10 young people in the control group (23%), eight in intervention 1 (16%) and 26 in intervention 2 (39%). For the other outcome measures at TP3, there were missing data again only for AUDIT and AUDIT-C in the intervention 2 arm – 6% and 1.5%, respectively. One young person failed to complete the A-SAQ in the control group.

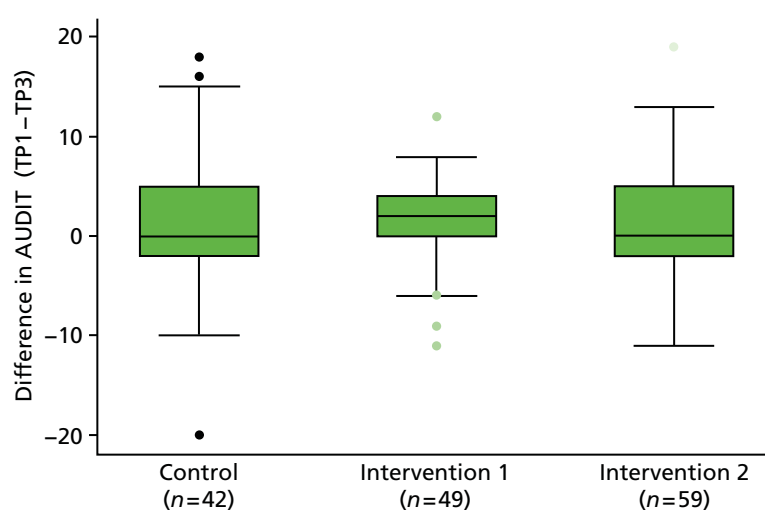


FIGURE 11 Distribution of individual change in AUDIT scores between TP1 and TP3 by trial arm.

Fidelity of the interventions

Fidelity of an intervention within research refers to the extent to which the intervention is true to the therapeutic principles on which it is based.¹⁷⁶ It requires the manualisation of the intervention wherein the philosophy, principles and procedures of the intervention are clearly described. This manual can then be used by the individuals delivering the intervention in order to deliver a standardised approach.¹⁷⁷ Moreover, a manualised intervention with verified fidelity enables the research to be replicated or the intervention to be implemented in practice.

Learning mentors were asked to record at least one session each; however, only six recordings of intervention delivery were made. In this study the BECCI was used to measure fidelity. BECCI is a tool developed specifically to measure the microskills of behaviour change counselling and MI.¹⁷⁸ The instrument focuses upon the practitioner's consulting behaviour and attitude rather than the patient's response. A qualified member of the team (RM) rated intervention 1 and intervention 2 audio-recordings. Rating was completed in line with the BECCI Manual for Coding Behaviour Change.¹⁷⁹ The mean BECCI score for the six recorded interventions was '2.5', which suggested that the learning mentors were all found to be delivering behaviour change counselling to 'some extent' or to 'a good deal' as assessed with the BECCI. The median BECCI score was '2.55', with the range 1.9–3.0 (individual scores were 1.9, 2.1, 2.3, 2.8, 2.9 and 3.0). Learning mentors typically performed well when discussing the risks associated with the young person's alcohol use. Lower scores were assessed when measuring microskills relating to discussing and exploring behaviour change. Future training of mentors in intervention delivery should focus upon discussing behaviour change with young people.

The small number of interventions that were recorded is a weakness that would need addressing in a full trial. In the feasibility study, learning mentors, randomised to either group other than the control, were approached and asked to record a minimum of one recording. A more formal approach to fidelity measurement is required. In a definitive study, learning mentors will be asked to record a simulated intervention with an actor immediately following training but before commencing the trial. Further training can then be provided on areas of practice weakness. A specific date will then be agreed for a further recording of intervention delivery with a trial participant.

Summary

The required number of schools (seven) were recruited into the feasibility pilot trial and retained at 12-month follow-up. Ninety-two per cent of young people in Year 10 (aged 14–15 years) across the seven schools completed the survey used to screen for inclusion into the trial. Sixteen per cent of those completing the survey met eligibility criteria and 80% of those eligible were recruited into the trial. Eighty-eight per cent of those recruited into the trial completed the 12-month follow-up. However, of the 75 recruited into the intervention 2 arm, only eight (10%) received both individual and family-centred interventions: the remainder received only the individual-level intervention (intervention 1). The trial arms were not well balanced on all variables at baseline, but this is not surprising for a cluster randomised trial with very few clusters and heterogeneity between clusters. There were very low levels of missing data on each score or variable at both baseline and 12-month follow-up. Furthermore the interview held to complete the 28-day TLFB was successfully achieved in all who attended the 12-month follow-up meeting with a learning mentor. Finally, there was some evidence that results on AUDIT, AUDIT-C and A-SAQ scales showed a slight shift to less alcohol consumption or risk behaviours at 12 months compared with baseline.

Chapter 6 Interviews with staff, young people and parents

Key points for Chapter 6

- Semistructured interviews were conducted with six lead liaisons, 13 learning mentors, 27 young people and seven parents ($n = 53$).
- Overall, the school was considered to be a feasible and acceptable environment to intervene with young people who are risky drinkers.
- Learning mentors were seen as being best placed to discuss alcohol with young people owing to their role within the school, their existing supportive relationships with young people and the trust that young people placed in them.
- The screening survey was found to be feasible, although in future work some consideration may need to be given to means of enhancing young people's privacy in order to increase acceptability.
- Intervention 1 was found to be feasible and mostly acceptable. Some learning mentors expressed hesitation at informing young people for whom their drinking placed them at risk of harm and the calorie-focused content resulted in mixed views from both learning mentors and young people.
- Intervention 2 did not appear to be feasible. 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 a benefit from doing so, and some young people who were interviewed told us that they did not want their parents involved.

For the integrated qualitative evaluation of the study, semistructured interviews were conducted with four key groups of participants: school lead liaisons; learning mentors; young people; and parents. This chapter begins with a description of the methods used in the conduct and analysis of these interviews, continues with a summary of the key findings, and concludes with a discussion of the overarching emergent themes from the qualitative phase of the study, alongside the limitations of the work.

Methods

Semistructured interviews were selected as the primary mode of qualitative data collection in order to inform a more in-depth understanding of the overarching research questions for the study. The aims for all sets of interviews were to explore the feasibility and acceptability of screening and BI approaches in the school setting, and to elicit participants' views on the study measures and processes used in delivering the project. Key topics for interviews with young people and their parents included consent procedures; parental involvement in interventions; the comprehensibility and burden of study measures and follow-up procedures; and the appropriateness of school-led health promotion work across the school-home interface. All interviews were conducted between May and August 2012. Each participant was interviewed once and interviews were timed to take place as soon as possible after their involvement in study procedures had ended. Interviews with lead liaisons, learning mentors and young people were performed and analysed by KL. Interviews with parents were performed and analysed by SS.

Sampling strategy

As this was a qualitative study, the aim of sampling was to achieve data saturation and maximum variation of perspectives. School lead liaisons were defined as the seven key individuals who made or brokered the decision about participation in the study on behalf of their school. As there were only seven lead liaisons involved, all were approached for interview. Purposive sampling was undertaken within the remaining three participant groups to ensure maximum variation within the study population. For learning mentor interviews, defined as the members of school staff trained in the delivery of the control condition/ interventions to participating students, sampling criteria were according to socioeconomic positioning of the school in which the learning mentor was used, and study condition.

For young people, sampling criteria were gender, socioeconomic status (SES) of school and the level of intervention received. SES and gender were considered important for this group because these factors are known to be related to drinking behaviour in this age group.¹⁸⁰ In addition, young people within the intervention 2 arm of the study were purposively sampled to include both those who agreed to family involvement and those who refused. This sampling frame resulted in 16 subgroups of young people to represent in interview.

For parent interviews, sampling criteria were SES of school and whether or not intervention 2 had successfully taken place. The latter criterion was included for two main reasons. First, there were a number of parents whom learning mentors had been unable to contact, using a range of different methods, to take part in a family intervention despite numerous attempts. Second, there were occasions when the parent agreed to take part in the intervention but the intervention did not take place, because either the parents or the young person changed their mind at a later date. It was felt that both of these groups of parents could give a useful insight into the complexities and dynamics of parental involvement in this form of intervention.

Recruitment and consent

A range of approaches was used in order to recruit interview participants into the study. Lead liaisons were approached directly by the researcher (KL) and learning mentors were, in turn, approached by their line manager (when not the school lead liaison) to ask if they would agree to be interviewed. Learning mentors acted as gatekeepers for interviews with young people, making the initial contact with the young person concerned, and setting up interview appointments on behalf of the researcher (KL). At each approach it was stressed that participation was entirely voluntary.

Learning mentors also helped facilitate access to parents for interview purposes. First, they contacted parents directly to confirm whether it was acceptable for a researcher (SS) to contact them about participation in an interview. If a parent had declined the family intervention (or learning mentors had struggled to contact them to arrange it), school staff attempted to contact them again (by phone, text message, e-mail and letter) to explain the purpose of interviews and to ask if their contact details could be given to the researcher. Parents were reassured that if they declined they would not be contacted about the study again.

Alternatively, if parents could not be contacted using these channels, learning mentors asked young people to invite parents for an interview and sent a message home with the young person, who was asked to provide contact information after checking with their parents that it was acceptable to pass this information on. It must be stressed that if young people withdrew their own consent for approaching parents then parents were not contacted to participate in an interview. Following an initial positive approach by the young person concerned, the researcher (SS) subsequently contacted parents, using a variety of methods (telephone, text message, e-mail and/or letter) to arrange interviews.

Interviews with lead liaisons, learning mentors and young people were all performed within their respective school setting. Interviews with parents took place at a time and place most convenient to the participant concerned. In practice, interviews were generally community based, comprising a mix of home interviews and interviews that took place in public locations, such as local coffee shops. One interview took place in the interviewee's place of work.

Informed consent was taken at the beginning of interviews, after ensuring that the interviewee had read the Participant Information Sheet and been given an opportunity to discuss any questions or concerns with the interviewer. Interviews lasted between 20 and 90 minutes and were all digitally recorded, with the resultant data transcribed verbatim by professional transcribers. All interviewees were allocated a participant reference code to ensure anonymity and confidentiality, and an anonymisation log was maintained.

Interviews with participants

Table 11 summarises the number of interviews by interview group, according to school and study condition. Six of the seven lead liaisons were interviewed as part of the qualitative evaluation of the study. The remaining lead liaison was on maternity leave during this period and could not be interviewed during the study time frame. Thirteen participating learning mentors were interviewed. The majority of participating learning mentors were female and this dynamic is reflected in interview participants (male = 2, female = 11).

In total, 27 young people were interviewed as part of this research (male = 12, female = 15). Every attempt was made to ensure that the sampling frame was saturated (i.e. at least one respondent arising from each cell). However, it should be acknowledged that the potential pool of young people who had agreed to intervention 2 was extremely limited, thus, in reality, all participants were approached for interview. In particular, there were no high SES males who agreed to intervention 2 and so it was not possible to interview a young person from within this category.

TABLE 11 Populated sampling frame for all subgroups

School (condition)	No. of participants			N
	Learning mentors	Young people	Parents	
G (control)	1	4	n/a	5
F (control)	2	4	n/a	6
E (level one)	2	4	n/a	6
A (level one)	1	3	n/a	4
D (level two)	3	4	3	10
C (level two)	2	4	1	7
B (level two)	2	4	3	9
N	13	27	7	47
n/a, not applicable.				

Finally, semistructured interviews were conducted with seven parents, all of whom were mothers. Three (of seven) schools were randomised to the intervention 2 arm of the study, with family members from these three schools invited to take part in an interview. Although it was initially anticipated that a mix of mothers, fathers and other nominated family members such as grandparents would participate in the intervention 2 family intervention, in practice, with the exception of one family intervention with a father, only mothers took part. One father (who said no to the family intervention) agreed to take part in an interview but later changed his mind upon the researcher's arrival. This parent appeared to be very uncomfortable with the prospect of taking part in an interview, stating to the researcher several times that his child did not drink and did not have a problem with alcohol. Six interviewees had taken part in a family intervention; one interviewee had not. This was because the young person did not want to give up their free time to take part and changed his/her mind – not because the parent said no. Although we set out to interview parents who did not participate in an intervention, owing to the small number of parents recruited to the parental component of intervention 2, interviews with parents proved the most challenging to arrange and there were clear barriers to participation. Nevertheless, despite interviewing only one non-participating parent, this account provided a rich and comprehensive insight into the complexities and dynamics of parental involvement. Further, the accounts of lead liaisons, learning mentors and young people were also instrumental in developing our understanding of parental involvement.

On completion of the 53 interviews it was deemed by the research team that data saturation had been reached: this was determined as the point at which no new themes were emerging from the interviews.

Data analysis

The interview data were analysed thematically,¹⁸¹ with the Framework approach, devised by Ritchie and Lewis,^{182,183} utilised to organise the analysis. The Framework approach, which is a structured organisation of themes, ensured that the analysis could be easily viewed and assessed by others in the research team.¹⁸⁴ Coding of transcripts was performed by the researchers who had conducted the interviews (KL for lead liaison, learning mentor and young person interviews; SS for parent interviews). A computer software program, such as NVivo, was not used during data analysis, as the research team felt that use of a program that 'cuts' the data into smaller chunks would inhibit us from looking at the data in its totality, risk information being taken out of its original context and potentially lead to 'over coding', through which a deeper level of interpretation is lost.¹⁸⁵ Instead, coding was performed by hand, using paper copies of transcripts. Later, resulting frameworks of codes were recorded in table format in a spreadsheet document. Each participant was listed as a column, and each code, and related subcode, listed as a row. When a participant discussed a code, the page and line number reference was placed in the relevant cell of the table. This enabled effective organisation, storage and retrieval of coded data. Each group of interviews was analysed separately from each other. Regular meetings were held with members of the research team with expertise in qualitative techniques to discuss and challenge emergent themes and exchange analytical thoughts. This is referred to as pragmatic double coding by Barbour.¹⁸⁶ The aim of these meetings was not to value one point of view over another, rather they aimed to 'maximise the analytic potential of exceptions or potential alternative explanations' (p. 1026).¹⁸⁶

Findings

Feasibility and acceptability within the school setting

For many of the schools, being involved in research was a familiar activity and something with which they felt comfortable. A strong finding was that it was highly important that contact about SIPS JR-HIGH came from a local university. Participants felt that they had existing relationships with Newcastle University, and they felt that they could trust this university to ensure a collaborative approach to the research.

Whereas other non-local universities might just have been seen to 'use' the school and the pupils (often this was from prior experience), Newcastle University could be trusted to feed back results to the school. Further, involvement with local universities was important in terms of raising aspiration for the pupils.

I feel we've got very strong relationship with Newcastle University, we've worked with you in the past doing research projects and I just always think I reserve my yes's for research, cause we can only do so much . . . Em, but no I just think I mean we've done, we've done, we've done a number of things over the years em, with Newcastle em, I just think it's always done well it's always done well its always done with a lot of thought the planning's always been excellent its always worked in the execution you get the impression there is a lot of kind of clout behind what's happening em, so no I, I don't know, I think partly it is the University em, and our relationship with them that kind of drives it a little bit.

Lead liaison, female

I think working with a local university you know we kind of feel like, I don't want to say simpatico but you know we feel like, we feel like there is that kind of, that relationship where you know you're very supportive of what, of what we're doing in schools and, and, and likewise we want to you know support, support you.

Lead liaison, female

The school was generally considered to be an appropriate setting for addressing alcohol use in young people. Parents acknowledged that schools offered great opportunity for positive influence upon young people as well as access to adults they could trust and talk to outside the home environment. Learning mentors and lead liaisons also viewed addressing alcohol use by young people as a legitimate function of the school. Indeed, a number of the learning mentors and lead liaisons highlighted that alcohol is part of a wider range of issues faced by young people, that are considered within personal, social and health education.

I'm not sure that things like risk-taking and behaviour can stand alone, they're actually more about self-esteem, personal development, resilience, identifying change, triggers, response, knowing that you'll have some dips and you'll have some dips, what can you draw upon motivationally yourself or with others to get back out. So I don't think and that's what happens quite a lot in education, you know the PSHE programmes like you know spring term year eight, week seven, road safety. I mean it's more around personal skills and personal development I think.

Lead liaison, female

Learning mentors in particular highlighted the opportunity that the school environment offered to intervene with young people regarding alcohol. However, a number of learning mentors questioned whether young people would feel able to discuss their alcohol use within a school setting, highlighting the fear of ramifications. Some young people commented on this issue also, questioning whether the school would share information with parents. Trust, therefore, was considered by learning mentors and young people to be important to the feasibility and acceptability of ASBI within a school setting.

Although it was suggested that a school should be responsive to its pupils' needs and both educate and care for the young people, members of staff cannot and should not fulfil all roles. There was a firm view that 'teachers should just teach', with both parents and young people reflecting that the authority that teachers hold within their role may be conflicted if they were privy to sensitive information relating to young people's alcohol consumption. The pastoral focus typically involved within the learning mentor role resulted in a sense that addressing adolescent drinking was compatible with their responsibilities. Parents in particular identified learning mentors as being the 'right' member of staff to deliver the intervention. Most of the learning mentors reported feeling comfortable discussing alcohol with young people, feeling

that they had legitimacy and adequacy within their role. Importantly, young people felt that they could talk to learning mentors about alcohol, with some commenting upon the existing relationship they have with learning mentors as well as the trust in sharing 'private' matters.

Because the mentors I know, he's really canny so we had a good talk about it. So he made us get all my questions out so it was fine after . . . Every time he sees me he just asks me how I'm doing and that, so it's fine, really. I'm not worried about what. Because he said it would be private so I'm fine with him knowing.

Young person, male

Almost half of the learning mentors reported that they had found it challenging to incorporate organising and delivering the intervention into their working week. For some, this difficulty related to restrictions being placed on when they could see the young people due to the academic curriculum. Contacting parents and children in order to organise the interventions was highlighted as being time-consuming. Others discussed unforeseen difficulties, such as a staff member being on sick leave. However, one learning mentor acknowledged that delivering intervention 1 to young people who had screened positive had been time-consuming, although she felt able to 'make time' for this within her role, owing to the importance she ascribed to the activity.

I mean that's just one of those things, [it was] much more than I thought it was going to be but I'd still do it again because I believe in it, if I believe in something then I'll make time for it.

Learning mentor, female

Although it was acknowledged that there was an additional burden of time, most learning mentors felt that they could feasibly include delivering ASBI within their role. One learning mentor reported ease at including the intervention in her working week:

I make my own timetable if you like. So I am not stuck to – I need to be here, here and here at certain times; so I can fit it in there. I can just go 'Right I will just clear my diary for two days and just see – and fit all them in'.

Learning mentor, female

Indeed, some learning mentors commented that they regularly address emotional and behavioural issues with young people within their current role and as such did not perceive addressing alcohol with young people to be an additional task.

A lot of the things we talk about at the moment aren't education related they're to do with could be self-esteem or stress or we've had chats with people about eating disorders things like that you know we've had deep, I'm saying we as in I'm talking about the mentors because we do a similar job you know what I mean, we have spoken about lots of different things so again its necessary in our job role it's not something that we sort of feel forced to do.

Learning mentor, male

Acceptability of the organisation and management of the study

Lead liaisons discussed their views of the initial approach by researchers regarding their potential involvement in the research project. This approach was viewed positively, with lead liaisons feeling that they were given enough information to enable them to make the decision regarding study participation. Further to this, lead liaisons talked favourably about the timing of the initial approach within the school timetable as well as the period of planning that had been incorporated into the study design:

I think it was fairly you know we'd had enough time to plan it, it wasn't as if 'oh can you do this next week?' There was plenty of time to sort of plan ahead.

Lead liaison, male

It just hit at the time. I think when [researcher] got in touch it was when I was thinking of the next year's curriculum and the next year's planning and I had time to sit and listen to what she was saying.

Lead liaison, female

Moreover, lead liaisons were also very positive about the continued support offered by the research team to the involved schools as the study progressed:

... er I mean there were things I came back to which is I say more like the nitty gritty you know how's it gonna happen you know, how are we going to do it type thing. Er and that was fine and that's where [researcher] came in and we worked with [researcher] on the best way of making sure that we reached the maximum number of young people.

Lead liaison, male

Acceptability of training

Lead liaisons and learning mentors spoke very positively about the training that they received as part of the study. Indeed, lead liaisons viewed the training, skill development and the potential benefit this would have upon the pupils to be an incentive to participate in the study:

So from my point of view I think the real driver was em, you know if students are identified with issues or problems or maybe just beginnings of that I knew that em, those students would be offered intervention with our learning mentors but the university very kindly had trained so they felt even more skilled up talking to students. And I just thought that has to be a positive end result for us.

Lead liaison, female

Learning mentors were trained as a group together, at a time and place that was most convenient to them. This provided valuable opportunities to learn from each other and discuss the issues raised by the training in a group of peers:

I think the training was perfect, going ... getting out the mix of going out of school for training and in school was good, going out for me because it meant that it was a break from in here and going somewhere else and em speaking with other people about it, like other learning mentors and seeing what other schools are involved. I thought that was really good. Em, and then the fact that you were able to come to us, that makes a huge difference. I don't think you would have had the response that you have had if it was constantly that we need to go over there.

Learning mentor, female

Further, the learning mentors felt that the training and associated documents, such as the manual, prepared them fully for the study:

No I thought, we were all trained very well and we had loads of paperwork, loads of information and loads of prompts which were excellent, you know, you could read through a stage one, two, three, four, step one, two, three right through erm, lots of ideas here that we could ask, and I thought, you know, we were very well prepared.

Learning mentor, female

In addition, the learning mentors and lead liaisons reported that they felt the after-training support was very important:

[Researcher] came in quite a lot as well and we managed, we had quite a lot of time to talk to her you know and get advice from her and information ... it was really handy to have her there to bounce questions off her and things like that so I felt that worked really well

Learning mentor, female

Importantly, study training and involvement was perceived to have a lasting benefit for the school. Learning mentors positively discussed benefits to their professional development, while one lead liaison reported intention to use the intervention tools within PSHE:

I thought they [intervention materials] were really good actually, no they were really really good. And I'm hoping that we might be able to use them actually. I've sort of shared them with the person, I hope its alright, with the person in PSHE who does that and there were certainly a lot of interesting ideas that we could develop from that sheet.

Lead liaison, male

Feasibility and acceptability of screening

Although most young people felt fully informed about the research project before taking part, some young people told us that teachers who were supervising did not always fully explain why the screening survey was taking place in their class. In particular, they were often unclear about the implications of including their name on the survey rather than anonymously, i.e. that they would be invited to an appointment with a learning mentor if they screened positive using a measure of hazardous and harmful alcohol consumption. This confusion is illustrated in the following quotes from young people:

I'm always used to doing tests and obviously you put your name down, and I thought it was a bit like a test really. I just put my name down, then when Miss called us I was like 'Damn it'.

Young person, male

... teacher just says, 'There's a questionnaire on your desk. Whoever fills it like in gets a £5 cinema voucher.' That's all he said.

Young person, male

In general, young people told us that they chose to participate in the research project 'to be helpful' rather than because they felt that they were in need of advice about alcohol.

Although lead liaisons reported that they were highly satisfied with the organisation of the screening survey with particular reference to the minimal impact it had upon teaching, a number of learning mentors questioned the feasibility and acceptability of this method. Learning mentors expressed some concern about confidentiality and the impact this may have upon accuracy of reporting, highlighting the potential for young people either to exaggerate or under-report their alcohol use. Indeed, a number of young people did comment that they were concerned that teachers or fellow pupils may read their answers over their shoulder. There were some young people who reported that 'there were quite a few people taking the mick with it, saying they were out every weekend drinking three bottles of vodka ...' (Young person, female). However, most young people who were interviewed stated that they did give honest and accurate responses about their drinking behaviour.

... if you're doing something that's about your well-being ... your like habits and stuff like that you've got to be mature about it; you've got to be serious. You can't be writing stuff like that on a survey. Like somebody's going to use for you know however long it is like feeding the results for and stuff like that. I just think it's a bit silly to be honest.

Young person, male

Nevertheless consideration must be given to young people giving social desirable answers, either to 'look good' to their friends or to give answers they think teachers want to hear:

What was really, erm, stood out that we look at, and I pointed, I pointed out to [researcher] is that they, we did ours in tutor groups, right, and you could actually see there was like between five and six people all out of the same tutor group, all the same peer group, I know they're all the same peer group, all in the same sort of sets, top sets, and they all came out as a band. One whole bunch, and you had to ask yourself, they would have been sitting next to each other when they did the survey, the original survey, and you, they probably asked each other, well, didn't we go such and such, didn't we do this, they'd have talked to each other about it.

Learning mentor, female

Feasibility and acceptability of intervention 1

Learning mentors praised the attractive design of the intervention 1 tool, the fact it enabled a logical yet flexible flow to the process of intervention delivery and, crucially, that it was engaging and interactive in style. Young people generally found the intervention acceptable, with some young people commenting that they found the advice given to be informative.

It contained the information that I needed and things that I wasn't sure about, it explained a lot. What alcohol does and how it can affect us. I think you need more things like that in school, talking about it more, because kids when I was thirteen you don't understand it.

Young person, male

There were, however, mixed views on the calorie-focused element of the intervention. Most learning mentors felt that discussing calorie content was a particularly effective way to engage with the young people. However it became apparent that a minority of learning mentors had avoided talking in any depth with young people about the calorie content of alcoholic drinks because of concerns that this could potentially exacerbate existing anxieties about weight. Young people expressed similar conflicting views with some reporting interest at this information, whereas for other young people who were concerned about weight, the calorie focus of the intervention did have unexpected consequences. They discussed ensuring they did not eat on the day of a drinking episode or going for a run the day after a drinking occasion to counteract the excess calories.

Intervention 1 is based upon the principles of MI. As discussed at length elsewhere, personalised feedback to help young people realise the risks associated with their specific drinking patterns is fundamental to the approach. Most learning mentors reported that they felt able to advise young people who had screened positive that their drinking placed them at risk of harm. Importantly, learning mentors reported that the intervention enabled young people to assess for themselves the amount of alcohol they were consuming. Moreover, young people commented that the act of writing down their drinking patterns and calculating the units made them see their drinking in a different way.

... because putting it on paper how many units I was taking in was quite bad. So with my exams coming through, I'm taking them now, it was like cut down.

Young person, male

Some learning mentors reported that they had avoided providing personalised feedback to young people on the risks associated with their alcohol consumption. In one school, learning mentors advised young people whom they had chosen at random, which is contradictory to the MI approach.

Feasibility and acceptability of intervention 2 (parental involvement)

Parental involvement was considered to be valuable to the intervention, as well as relationships between the school and the family (by some learning mentors and lead liaisons). A number of learning mentors described communicating with and involving parents as a standard part of their role. However, others anticipated major barriers to parental involvement, and were concerned that it crossed an 'unspoken boundary' in relation to the school-home divide. Indeed many learning mentors involved in delivering intervention 2 reported that it had been difficult to contact parents to discuss participation, with parents not responding to telephone and written contact about the study. Others advised that some parents did not attend appointments arranged. Furthermore, there was a concern that only those young people and parents in lesser need of support around alcohol use would take part ('lower' level drinkers with positive parental relationships). This was contrasted with the parents and young people most in need of an alcohol intervention who were seen as unlikely to participate ('higher' level drinkers with more problematic family dynamics):

... the parents of the kids you really need to see tend not to turn up ... You know so I don't feel as though we got the ones, and the ones that were on the list didn't want their parents involved, they were probably ones that you know, were the park drinkers or the you know that did it behind somebody's back.

Learning mentor, female

Young people who agreed to their parent(s) being involved in the intervention reinforced this belief, reporting that their parents had existing knowledge about their drinking and this was the primary factor influencing their participation in intervention 2. In contrast, if their parent did not know about their drinking then young people were far less inclined to consent to a family intervention session.

If my mum had no idea about my drinking and she came in and we had to discuss it. I don't know how I would've dealt with that.

Young person, female

... it is just a private part, which is why I didn't want to bring her in.

Young person, female

Further, participating parents often questioned the relevance of intervention 2 to their individual situation. In particular, parents interviewed felt they already benefited from an open and trusting relationship between themselves and their child and as such, were 'not the right type' of people to be involved: intervention 2 did not teach them anything that they did not already know.

I mean it's not really something that affects us a great deal, we're possibly not the right people for you to be talking to, because it doesn't have much of an impact on our lives ... for what you're trying to gain from this we might not be the right people to talk to because we're open, we talk about everything and it's not an issue in our house.

Parent, female

Rather than consider the involvement of parents in intervention 2, the learning mentors, young people and parents shared the view that the intervention was not effective in engaging the parents and young people who may benefit from this intervention. Parental motivation for participation was based upon assisting the school in research and was not considered to be beneficial in addressing risky drinking by young people. Importantly, parents and young people did not express a desire to engage in intervention 2 or a benefit from doing so.

Summary

It would seem that the school is both a feasible and an acceptable environment to intervene with young people who are risky drinkers. Learning mentors in particular are well placed to discuss alcohol with young people owing to their role within the school, their existing supportive relationships with young people and the trust that the young people place in them. Although it is acknowledged that the delivery of the interventions can be time-consuming, there was the sense that the activity remains feasible. The training provided to learning mentors was considered to fully prepare them for their role within the study. Importantly, acceptability of intervention delivery was high; intervening with young drinkers was often seen as important and necessary aspects of the learning mentors' work.

Overall, the screening survey was found to be feasible, although in future work some consideration may need to be given to means of enhancing the young people's privacy in order to increase acceptability. Teachers were often present, overseeing the class while the young people completed the screening survey. These teachers had not been trained in best-practice approaches to this research method, however, and had received only minimal information regarding the purpose of the 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 was found to be feasible and mostly acceptable. Some learning mentors expressed hesitation at informing young people for whom their drinking placed them at risk of harm, choosing instead to advise the young people who had been selected at random. This is suggestive of an outstanding training need for the learning mentors. As such, future work should ensure that the training programme emphasises the importance of personalised feedback within the delivery of interventions. The calorie-focused content also resulted in mixed views from both young people and learning mentors. As this information is not central to the information, it is recommended that this is not included in an intervention within a definitive trial.

It would appear that intervention 2 is not feasible. Parents and young people did not express a desire to engage in this intervention or a benefit from doing so. Moreover, learning mentors, parents and young people questioned the utility of an intervention which 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 young people and their parents who were offered did not participate in this intervention. Some young people interviewed told us that they did not want their parents involved. Although we did not interview any parents who chose not to participate in intervention 2, quantitative data presented elsewhere in this report reinforce the findings of the qualitative study that intervention 2 is not feasible, as well as suggesting that it is not acceptable to a large group of young people and parents. Furthermore, by not including an intervention that involves parents in future work, the time-consuming task of contacting parents, arranging appointments and rearranging appointments that are not attended would be alleviated, thus enabling learning mentors to use their time more efficiently.

Chapter 7 Health economics

Key points for Chapter 7

- The collection of data using the open-ended case diary tool highlighted a number of problems. A structured case diary tool would both be more precise and provide more reliable data while also reducing the data collection burden on the learning mentors in a definitive trial.
- Percentages of missing data for service use questions from the three survey time points do not seem to be problematic, suggesting that the tool is acceptable for use with young people in a definitive trial.
- However, some thought should be given to how we measure service use, especially in relation to certain categories (i.e. GP visits).
- It appears that the EQ-5D is an appropriate tool to use with young people. The majority of young people indicated that they had no problems on the first three dimensions of the EQ-5D-Y (mobility 93%; looking after self 99%; doing usual activities 94%).
- Higher levels of problems were found in the dimensions of pain or discomfort (19% having some level of problems) and being worried, sad or unhappy (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.

This chapter presents findings from the health economics component of the study that aimed to rehearse the methods of data collection to inform the development of the economic evaluation in a definitive study. The definitive health-economic analyses will show how the costs of introducing and running the BI compare with the current practice; the reason for this is that a full economic evaluation should include current practice as a comparator, as it seeks to inform decisions about whether we should move from current practice to something else.¹⁸⁷ The analyses reported in this section will be used to produce the protocol for a definitive trial and attendant economic evaluation of the impact of brief alcohol intervention compared with standard practice (PSHE) in a school setting to reduce alcohol-related risk or harm.

This chapter focuses on examining what resource-use data we should collect and how these will be analysed. The focus is on the key elements of an economic evaluation, which are costs and consequences, which will be discussed below. The level of completeness of the data has been analysed and the suitability of tools is commented on accordingly. In each of the following sections the results of our analysis are presented with associated discussion and recommendations.

Sections of analysis

Costs Resources and costs required to provide the intervention.

Outcomes/consequences Health-economic outcomes of the intervention including NHS and public services resource-use and health-related quality of life (as measured by EQ-5D-Y).

The health-economic outcomes are based on the participant-completed questionnaires, specifically questions 14 (Resource Use) and 15 (EQ-5D-Y), administered as part of the non-randomised repeat cross-sectional survey. These data were collected at the three survey time points: TP1, TP2 and TP3. Questions 14 and 15 were not separately identifiable for the subgroup of survey participants at TP2 or TP3 when they were followed up within the trial. This pilot trial intended to test only the alcohol-related outcomes at 12 months for the trial participants. Therefore, the data we have available is for the entire survey cohort at these three time points, which is appropriate from a health-economic perspective, as our objectives were met and no economic evaluation was planned in this feasibility study.

Costs

Analysis of resources use and costs associated with both intervention (intervention 1 and intervention 2) and control groups relate to two specific areas: the resources required to provide the intervention; and the resources used subsequently after the intervention (or control). The details of such costs and resources are discussed below.

Intervention cost

Staff cost of intervention

A main resource-use component of the economic evaluation (for a definitive trial) will be the cost of learning mentor time required to prepare for and deliver the BI to young people (and, for intervention 2 only, the session with parents) and to conduct the necessary follow-up with the young people thereafter. Time spent for the feasibility study was calculated by observing the average minutes per case (i.e. young person) as documented in a self-completed case diary. The appropriateness of the case diary tool is assessed according to rates of completely missing data (i.e. unused diaries) and of diaries missing relevant information. The rate of salary (plus employer on costs, such as superannuation and national insurance) will be, in a definitive trial analysis, applied to average learning mentor time, as discussed further below. In this subsection, the case diary result tables are analysed and discussed.

To pilot the case diary tool, we used an open-format diary (shown in *Appendix 6*). The reason for this decision was twofold; first, having the tool in an open-ended format gave the learning mentors the opportunity to describe the categories of activity to which they were devoting their time, and, secondly, it provided information on how long it took to complete these activities. The original intention was to use the open-ended version of the tool used in the feasibility study in the definitive trial; however, a lesson learned was that it was possible (using the data collected with the original tool) to develop a simpler revised tool that would collect the same level of information but be quicker and easier to complete as well as simplifying data entry and analysis.

Overall, in practice, the open format is appropriate for a pilot but is not ideal in a definitive trial owing to its limitations, which are discussed and explored below and further in the discussion. Although a categorically structured, close-ended format is a preferred choice, we could not have designed an appropriate time diary tool without piloting an open-ended case diary first. For the definitive trial, the new tool should be piloted with learning mentors before being confirmed.

Results

As the primary objective of these data is to inform the design of a more appropriate time diary tool, *Tables 12–14* describe the intention-to-treat analysis results, in which groups are compared in terms of how young people were randomised. Solely using an intention-to treat-analysis within clinical trials has its limitations,¹⁸⁸ but, as our objective was to assess how appropriately the case diary tool was used for resource-use collection, it is acceptable in this case.

Tables 12–14 display the results in two categories within each table, the first category (shown in shaded columns) being how often and how appropriately the case diaries were used as assessed by rates of missing case diaries, rates of partially completed case diaries, and rates of students withdrawn from the study. The second category shows what the results of the completed case diaries were in minutes, as reported in the five-number summary statistics. The summary statistics are shown by the categories created by the decision rules of the research staff (i.e. 'Prep', delivery).

The purpose of the first category is to show how the open-ended format case diaries were actually used by the learning mentors to inform what categories need to be included in the definitive time diary. 'Total missing' was concluded when a learning mentor did not use his/her case diary at all, whereas 'Category missing' was concluded by decision rules set by the research staff. For example, in the first line

TABLE 12 Time recorded by learning mentors: intention to treat – control

Control (in minutes)											
Intention to treat	N	n	% total missing ^a (n)	% category missing ^b (n)	% withdrawn/session did not take place (n)	Minimum	Lower quartile	Median	Upper quartile	Maximum	
Control arm with young person											
Prep (case diary)	53	2	1.9 (1)	94.3 (50)	–	5.0	5.0	5.0	5.0	5.0	
Delivery (case diary)	53	52	1.9 (1)	–	–	7.0	10.0	13.75	15.0	15	
Intervention total	53	52	–	1.9 (1)	–	7.0	10.0	13.75	15.0	20.0	
Follow-up ^c											
Prep	53	1	26.4 (14)	54.7 (29)	17 (9)	1.0	0.50	1.0	0.50	1.0	
Delivery (case diary) ^d	53	30	26.4 (14)	–	17 (9)	5.0	7.5	10.0	15.0	20.0	
Delivery (TLFB form) ^d	53	36	15.1 (8)	–	17 (9)	1.0	2.0	7.5	10.0	20.0	
Follow-up total	53	34	5.7 (3)	13.2 (7)	17 (9)	5.0	7.5	10.0	15.0	20.0	
Control total	53	53	–	–	–	10.0	15.0	20.0	25.0	35.0	

^a Diary not used by the learning mentor.

^b Some categories of diary were not completed by learning mentor.

^c Data for delivery were taken from two sources and the longer of the two was recorded in the total.

^d Rates of 'Total missing', 'Category missing' and 'Withdrawn/session did not take place' are different for this category, as new blank case diaries were given to the learning mentors at this stage.

a Diary not used by the learning mentor.

b Some categories of diary were not completed by learning mentor.

c Data for delivery were taken from two sources and the longer of the two was recorded in the total.

d Rates of 'Total missing', 'Category missing' and 'Withdrawn/session did not take place' are different for this category, as new blank case diaries were given to the learning mentors at this stage.

TABLE 13 Time recorded by learning mentors: intention to treat – intervention 1

Intervention 1 (in minutes)										
Intention to treat	N	n	% total missing ^a (n)	% category missing ^b (n)	% withdrawn/session did not take place (n)	Minimum	Lower quartile	Median	Upper quartile	Maximum
<i>Intervention 1 with young person</i>										
Prep (case diary)	54	23	–	57.4 (31)	–	3.0	5.0	15.0	20.0	70.0
Delivery (case diary)	54	54	–	–	–	15.0	25.0	30.0	32.0	50.0
Time (intervention sheet)	54	53	1.9 (1)	–	–	5.0	20.0	25.0	30.0	90.0
Intervention total	54	54	–	–	–	15.0	30.0	30.0	41.25	90.0
<i>Follow-up^c</i>										
Prep	54	21	–	53.7 (29)	7.4 (4)	5.0	5.0	5.0	10.0	30.0
Delivery (case diary) ^d	54	49	–	1.9 (1)	7.4 (4)	3.0	10.0	18.0	20.0	40.0
Delivery (TLFB form) ^d	54	39	22.2 (12)	–	5.6 (3)	3.0	10.0	11.0	20.0	55.0
Follow-up total	54	50	–	–	7.4 (4)	3.0	15.0	20.0	25.0	60.0
Intervention 1 total	54	54	–	–	–	18.0	40.0	54.0	65.0	120.0

^a Diary not used by the learning mentor.

^b Some categories of diary were not completed by learning mentor.

^c Data for delivery were taken from two sources and the longer of the two was recorded in the total.

^d Rates of 'Total missing', 'Category missing' and 'Withdrawn/session did not take place' are different for this category, as new blank case diaries were given to the learning mentors at this stage.

TABLE 14 Time recorded by learning mentors: intention to treat – intervention 2

Intervention 2 (in minutes)										
Intention to treat	N	n	% total missing ^a (n)	% category missing ^b (n)	% withdrawn/session did not take place ^c (n)	Minimum	Lower quartile	Median	Upper quartile	Maximum
Intervention 2 with young person										
Prep (case diary)	75	46	9.3 (7)	29.3 (22)	–	1.0	5.0	10.0	12.75	220.0
Delivery (case diary)	75	69	8.0 (6)	–	–	5.0	20.0	30.0	30.0	99.0
Time (intervention sheet)	75	69	8.0 (6)	–	–	10.0	20.0	30.0	30.0	60.0
Intervention total	75	74	–	1.3 (1)	–	6.0	25.0	31.0	45.0	255.0
Family meeting										
Prep (case diary)	75	69	–	8.0 (6)	–	0.0	0.0	0.0	0.0	47.0
Delivery (case diary)	75	70	–	6.7 (5)	–	0.0	0.0	0.0	0.0	40.0
Time (intervention sheet)	75	75	–	–	–	0.0	0.0	0.0	0.0	40.0
Family meeting total	75	75	–	–	–	0.0	0.0	0.0	0.0	85.0
Follow-up ^c										
Prep	75	47	16 (12)	12 (9)	9.3 (7)	1.0	1.0	5.0	8.0	45.0
Delivery (case diary) ^d	75	56	12 (12)	–	9.3 (7)	0.0	10.0	11.0	15.0	25.0
Delivery (TLFB form) ^d	75	48	28 (21)	–	8 (6)	0.0	13.50	20.0	20.0	30.0
Follow-up total	75	64	5.3 (4)	–	9.3 (7)	1.0	15.0	20.0	25.0	57.0
Intervention 2 total	75	75	–	–	–	12.0	34.0	52.0	68.0	270.0
<div>a Diary not used by the learning mentor.</div> <div>b Some categories of diary were not completed by learning mentor.</div> <div>c Data for delivery were taken from two sources and the longer of the two was recorded in the total.</div> <div>d Rates of 'Total missing', 'Category missing' and 'Withdrawn/session did not take place' are different for this category, as new blank case diaries were given to the learning mentors at this stage.</div>										

^a Diary not used by the learning mentor.

^b Some categories of diary were not completed by learning mentor.

^c Data for delivery were taken from two sources and the longer of the two was recorded in the total.

^d Rates of 'Total missing', 'Category missing' and 'Withdrawn/session did not take place' are different for this category, as new blank case diaries were given to the learning mentors at this stage.

of *Table 12*, out of '*N*' diaries (53), two learning mentors reported preparation ('Prep') time before performing the intervention, therefore '*n*' is two for the 'Prep' category.

The purpose of the second category (five-number summary statistics for *n*) within *Tables 12–14* was to observe the range of minutes, as recorded by the learning mentors, so that an appropriate choice of times could be presented on a structured time diary for the definitive trial. To ensure that accurate time ranges were presented, the follow-up time was taken from an additional source (TLFB), with the research staff making the decision rule that the longer of the two times would be recorded. In the definitive trial, the TLFB form will not be used to record the intervention time to reduce administrative burden on the learning mentors. To simplify the process, the learning mentors will be instructed that the only place to record time spent on the intervention is the time diary.

In summary, the collection of data using the open-ended case diary tool highlighted a number of areas in which a more detailed case diary tool would be both more precise and provide more reliable data, while also reducing the data collection burden on the learning mentors. For example, 'Category missing' was consistently higher than 'Total missing' across study arms, which shows that the learning mentors were using the diaries but were not as likely to list categories specifically. In a full economic evaluation it is important to be able to collect resource use for the different aspects of the intervention, and this will more likely be achieved with a more structured time diary (such as the template in *Appendix 6*) in a definitive study.

Collection of data relating to learning mentor time via the open-format case diary (see *Appendix 3*) had a number of limitations:

1. Use of open-format diaries meant that differing levels of data were reported by learning mentors, especially in relation to preparation time. Open-format diaries were used in the study, as learning mentors were asked to record every time they attempted to contact, or successfully made contact with, the young person on this document. This enabled the research team to look at how long was spent arranging and carrying out the interventions.
2. Learning mentors changed mid-case, as shown in *Table 15*. It was not possible to conclude if such changes affected the completion of diaries. In addition, potential factors, such as training differences or staff changes, are not possible to examine.
3. Missing data cannot be accurately assessed. Learning mentors were given new case diaries at the different stages of the intervention. For example, a blank case diary was given to the learning mentor before the intervention and again before follow-up. Although case diaries were coded to the trial participant, and could be linked at both stages in the intervention, the diary may have been completed differently at different time points. For example, differences in staff workload or time pressure (i.e. how busy the learning mentor was) could have affected the level of data recorded, as could whether the learning mentor conducting each stage of the intervention had changed (i.e. differences in conduct between learning mentors).

TABLE 15 Change in allocated learning mentor from baseline to follow-up

Condition	Learning mentor stayed the same, <i>n</i> (%)	Change in learning mentor, <i>n</i> (%)	Total with learning mentor name known at follow-up, ^a <i>n</i> (%)
Control	9 (20.5)	35 (79.5)	44 (100.0)
Intervention 1	50 (100.0)	0 (0.0)	50 (100.0)
Intervention 2	27 (42.2)	37 (57.8)	64 (100.0)
<i>Total</i>	86 (54.4)	72 (45.6)	158 (100.0)

^a Totals not including cases in which the young person withdrew from the study or the learning mentor did not use the diary (missing data).

4. 'Category missing' was used in data coding as an indicator of when learning mentors did not, in the open-format case diary (see *Appendix 3*), provide all of the time data for each of the aspects of the intervention. This is not surprising, as one role of the case diary used in this feasibility study was to identify what aspects of the intervention might be provided. It should be noted that, although the research team made the decision rule regarding what was an incomplete or 'Category missing' section of the case diary, directions to include certain categories were not included anywhere on the case diary form to direct learning mentors to do so (see *Appendix 3*).
5. Times for the delivery of the intervention were taken from both case diaries and intervention materials in which learning mentors were asked to report the start and finish time in both places. The intervention times from both tools were not always the same. When coding the data, a decision rule was adopted to choose the longer of the two intervention times to inform the total.

Learning mentor training time

Training for learning mentors will be provided by SIPS JR-HIGH research staff on site at all locations. The time to deliver the training, per location, will be documented by the SIPS JR-HIGH research staff in hours and minutes (i.e. 2 hours 15 minutes). A list of learning mentors in attendance will be recorded so that the training time (cost) per learning mentor can be incorporated into the cost of running the intervention. The learning mentors are not to record this training time in the intervention time diaries under the 'Prep' category, as that category is referring to intervention casework, not the training time. The SIPS JR-HIGH research staff delivering the training will record their time and pay grade so that the cost data can be incorporated into the analysis. In the definitive trial, the SIPS JR-HIGH research staff will keep a record of all time spent on training follow-up which is specifically related to the training of learning mentors. The methods to calculate these costs are discussed in the next section.

Resource-use and unit-cost information

To assess the full cost of the intervention to inform the definitive economic evaluation, both resource-use and unit-cost data will be collected and reported in tables similar to *Tables 16* and *17*. These tables illustrate an example for a single area of resource use and its associated unit cost. For the definitive trial, full tables will be populated with all applicable measures of intervention resource use and unit costs will be reported. For this feasibility study, the resource-use data and unit-cost sources are not reported as the definitive trial will go beyond the local authority school district.

In the definitive trial, once the tables have been populated with all relevant resource-use categories and corresponding unit costs, the two tables will be used together to calculate the total cost of running the intervention. All cost outputs will be reported in UK pounds sterling for the final financial year of the

TABLE 16 Example template for obtaining unit-cost data for definitive trial

Resource category	Unit-cost source ^a
Example: learning mentor training time	Example: average learning mentor salary cost to a local authority area – around £21,482 per annum
	Assuming 46 contracted weeks per year and 37 hours per week at Grade 6, Point 22–24: £20,800–22,165
	Of above average amount, approximately: £4296.00 are estimated to be on-costs ^b
<p>a Examples are for illustrative purposes to illustrate how the unit-cost data will be sourced; actual cost and contract information will be sourced from the participating local authorities in the definitive trial.</p> <p>b On-costs: employer's contribution to national insurance and superannuation plans.</p>	

TABLE 17 Staff cost-per-minute formula

Average annual salary	Plus on-costs (i.e. employer's contribution to national insurance, pension/superannuation)	= No. of working weeks per year ^a (divide by 46)	= No. of work hours per week ^b (divide by 37)	Divide by 60 minutes = per-minute cost of learning mentor time
£17,185.00+	£4296.00	= £467.00	= £12.62	£0.21

SA, superannuation; NI, employer's contribution to national insurance.
^a Estimated contract of 46 weeks per annum.
^b Estimated contract of 37 working hours per week.

definitive study. For example resource-use data (i.e. 45 minutes of learning mentor time) is multiplied by the unit-cost data from *Table 17* (i.e. cost per minute of a learning mentor) to calculate the monetary cost of that particular resource use. The data are an estimation of salary and on-costs (based on local authority data) to show the process that will be taken for the costing portion of a future full economic evaluation. For a definitive trial, these data will be sourced by school district centrally through their learning platforms. Cost per minute of staff time will be derived using the formula illustrated in *Table 17*, which shows that the average resource use for the learning mentor training portion of the intervention would cost £9.45 per learning mentor (45 minutes × £0.21).

Outcomes

Resource use subsequent to the intervention

Questions 14.1–14.6 in the questionnaire completed by young people at TP1, TP2 and TP3 are self-completed resource-use questions relating to use of NHS, criminal and social services (see *Appendix 3*). Survey participants reported how often in the last 6 months they used a particular health-care or public service. A decision was made regarding whether the evaluation should include data that are attributable only to alcohol use or to all services. It was decided to focus on all service use for two main reasons. First, it was deemed appropriate that all service use was to be captured because attributing use to alcohol would increase the burden on respondents and add in a possible extra element of recall bias. The second, and more important, explanation is that there may be subtle reasons why the use of services differs even when not directly attributable to alcohol use (e.g. use of services is higher because of poorer health caused by higher rates of alcohol use).

In a definitive trial, all service use will be associated with a monetary cost, which will inform portions of the economic evaluation. For this feasibility study no monetary costs were calculated from these data; rather, the data have been reported as a set of descriptive statistics that illustrate the appropriateness of the tools used in the pilot study. The collection of these data within the definitive RCT setting will use recognised and robust methods that should ensure that the data collected is equally accurate in both trial arms and hence the difference in costs is sufficiently robust to inform policy decisions.

Descriptive statistics

Table 18 shows survey data at the following survey time points. For all TP1, TP2 and TP3 variables the percentage of missing and implausible values are reported, along with the five-number summary statistics. The percentage of implausible values and missing data was reported as a percentage of the total cohort groups (*N*) then removed from the total when calculating the remaining summary statistics (*n*). Therefore, percentages are based on available data. For *n*, the five different summary statistics are produced (minimum, lower quartile, median, upper quartile, maximum).

The appropriateness of the self-completed questionnaire has been assessed by completion rates, missing data and implausible values. Use of services was generally very low. The majority of participants reported no use of services, although for all services a small number reported some use. The only possible exception to this is visits to the GP which, as might be expected, were more frequent, although still uncommon.

TABLE 18 Resource use of young people at TP1, TP2 and TP3: summary statistics

Variable name	N	% (n) missing	% (n) implausible values ^a	n	Minimum	Lower quartile	Median	Upper quartile	Maximum
TP1: baseline									
School nurse visits	1280	4.2 (54)	0.9 (12)	1214	0	0.0	0.0	0.0	6
Accident and Emergency visits	1280	4.2 (54)	1.6 (21)	1205	0	0.0	0.0	0.0	6
Admitted to hospital	1280	4.5 (58)	0.9 (12)	1210	0	0.0	0.0	0.0	6
Visited GP	1280	4.8 (61)	3.7 (47)	1172	0	0.0	0.0	2.0	6
Visited by social worker	1280	4.5 (57)	0.7 (9)	1214	0	0.0	0.0	0.0	6
Times arrested	1280	4.2 (54)	0.9 (12)	1214	0	0.0	0.0	0.0	6
TP2: 6-month follow-up									
School nurse visits	1256	6.2 (78)	1.75 (22)	1156	0	0.0	0.0	0.0	6
Accident and Emergency visits	1256	6.4 (81)	2.8 (35)	1140	0	0.0	0.0	0.0	6
Admitted to hospital	1256	6.7 (84)	2.1 (26)	1146	0	0.0	0.0	0.0	6
Visited GP	1256	6.6 (83)	4.4 (55)	1118	0	0.0	0.0	2.0	6
Visited by social worker	1256	6.6 (83)	1.0 (12)	1161	0	0.0	0.0	0.0	5
Times arrested	1256	7.0 (88)	1.8 (22)	1146	0	0.0	0.0	0.0	6
TP3: 12-month follow-up									
School nurse visits	1161	4.0 (47)	2.4 (28)	1086	0	0.0	0.0	0.0	6
Accident and Emergency visits	1161	4.0 (46)	2.8 (32)	1083	0	0.0	0.0	0.0	6
Admitted to hospital	1161	4.3 (50)	1.6 (18)	1093	0	0.0	0.0	0.0	6
Visited GP	1161	4.0 (47)	5.0 (58)	1056	0	0.0	0.0	2.0	6
Visited by social worker	1161	4.3 (50)	1.0 (12)	1099	0	0.0	0.0	0.0	6
Times arrested	1161	4.6 (53)	1.6 (19)	1089	0	0.0	0.0	0.0	5
a Set at seven or more contacts in last 6 months.									

Implausible values were based on the distribution of the data; there was an observable 'drop off' with scores of > 6 . We therefore defined the data at seven or over as an 'implausible value'. For the definitive trial, the data will not be observed before analysis, but in this feasibility study we used the data collected to inform decision rules that may also be most appropriate for the definitive trial.

As a result of the analysis the following can be concluded:

1. Although no guidance exists as to what level of missing data is likely to be important, we have calculated the percentages of missing data from the three time points and they do not seem to be problematic, suggesting that the tool is acceptable for use with young people.
2. The level of implausible values at $\geq 7\%$ may be problematic for certain categories (i.e. GP visits). For the rest of the resource-use questions, the percentages of implausible values did not appear to be problematic, based on the summaries in *Table 19*.

European Quality of Life-5 Dimensions (Youth version)

The EQ-5D-Y was developed as a child-friendly version of the EQ-5D, which is a quality-of-life measure used extensively in economic evaluations. For this pilot, the EQ-5D-Y was chosen as it is especially designed for young people; the main difference relates to the wording of the most severe level for activities of daily living. Using the EQ-5D is in line with NICE's Public Health Methods Guidance and may well be a benchmark for methods by which this intervention will be assessed. The tool divides health status into five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Each of these dimensions has three possible levels giving 243 possible health states. The EQ-5D-Y does not currently have a utility value set to assign to responses, which was not an issue in this case for the following reasons. First, in the feasibility study, the objective was to look at the completion rates of the health-economic tools, therefore the EQ-5D-Y algorithm-derived health-utility scores are not to be reported; rather the five-number summary statistics are reported for the ordinal responses (1–3) to each of the five questions contained within the EQ-5D-Y. Second, since the time of the pilot we have received clarification from the Euroqol group that EQ-5D (the standard version) is valid for use in participants aged ≥ 12 years. We will therefore use the EQ-5D in place of the EQ-5D-Y. Nevertheless, owing to the similarity of the two tools the findings from the feasibility study are still informative.

Within the definitive study, responses to the EQ-5D questionnaire will be transformed using a standard algorithm¹⁸⁹ to produce a health-state utility at each time point for each patient. From these data, quality-adjusted life-years (QALYs) for each participant will be calculated using the area-under-the-curve approach. From these data, the mean QALY score for each group can be calculated. There are concerns that the EQ-5D may not capture all relevant outcomes but, as discussed in the subsection below, considerable variation in young people's responses to the EQ-5D-Y were observed and it is therefore plausible that it will capture important differences.

TABLE 19 Comparison of means of implausible data

Time point	Average (%) implausible values: ^a all other resource-use questions except GP visits	(%) implausible values: ^a GP visits
Baseline	1.0	3.0
TP1	1.89	4.4
TP2	1.88	5.0
^a Set at seven or more contacts.		

Descriptive statistics

The descriptive statistics from the EQ-5D-Y ordinal values (1–3) are reported and the suitability of the EQ-5D for the definitive trial will be assessed from the perspective of completion rates and missing data. For TP1, TP2 and TP3 the percentage of missing variables is reported. For the EQ-5D-Y, given the phrasing of questions, it was assumed that any response from the three categories for each question (no problems, some problems or a lot of problems) would be valid (*Table 20*).

The rates of missing data are not problematic, as they appear to be consistent across dimensions at each time point. Overall, it appears that the EQ-5D is an appropriate tool to use with young people. Not surprisingly, most young people answered that they had 'no problems' on the first three dimensions: mobility, looking after self and doing usual activities, although there was a larger percentage of students reporting having 'Some' or 'A lot' of problems in the last two dimensions: 'Pain and discomfort' and 'Worried, sad or unhappy'. This suggests that there is some opportunity for the trial interventions to improve health at least in terms of the last two dimensions of the EQ-5D. It is unlikely, however, that a definitive trial could demonstrate any improvement in the first three dimensions unless it were very large.

Cost-consequence analysis

In the definitive trial, if there is not a significant change in health-state utility attributable to the intervention, the trial analysis can also include a cost-consequence analysis. The cost-consequence analysis will allow a focus on a wider range of outcomes than just health and will seek to consider costs and outcomes beyond the trial end point. The results of the analysis will be presented as a balance sheet.¹⁹⁰ The principle underpinning a balance sheet is that the analyst should seek to capture all costs and benefits no matter on whom they may fall – the same principles underpinning a cost-benefit analysis.¹⁹¹ Although not included in the feasibility trial, data on the use of 'educational services' will be elicited via the questionnaire.

TABLE 20 European Quality of Life-5 Dimensions (Youth version): summary statistics

EQ-5D-Y	N	Missing, % (n)	n	No problems, % (n)	Some problems, % (n)	A lot of problems, % (n)
TP1: baseline						
Mobility	1280	3.4 (43)	1237	93.3 (1155)	5.9 (73)	0.7 (9)
Looking after self	1280	3.4 (43)	1237	98.7 (1222)	0.6 (7)	0.6 (8)
Doing usual activities	1280	3.4 (43)	1237	94.1 (1164)	5.1 (63)	0.8 (10)
Pain or discomfort	1280	3.5 (45)	1235	81.0 (1000)	17.2 (213)	1.8 (22)
Worried, sad or unhappy	1280	3.9 (50)	1230	75.5 (929)	20.7 (255)	3.7 (46)
TP2: 6-month follow-up						
Mobility	1256	5.9 (74)	1182	92.8 (1097)	5.6 (66)	1.6 (19)
Looking after self	1256	6.0 (75)	1181	98.1 (1158)	1.0 (12)	0.9 (11)
Doing usual activities	1256	6.1 (77)	1179	92.7 (1093)	6.0 (71)	1.3 (15)
Pain or discomfort	1256	6.2 (78)	1178	77.7 (915)	20.0 (236)	2.3 (27)
Worried, sad or unhappy	1256	6.2 (78)	1178	70.1 (826)	25.0 (294)	4.9 (58)
TP3: 12-month follow-up						
Mobility	1161	1.5 (17)	1144	92.4 (1057)	5.9 (67)	1.7 (20)
Looking after self	1161	1.6 (18)	1143	97.1 (1110)	1.2 (14)	1.7 (19)
Doing usual activities	1161	1.6 (18)	1143	93.4 (1068)	4.7 (54)	1.8 (21)
Pain or discomfort	1161	1.6 (19)	1142	77.8 (888)	19.0 (217)	3.2 (37)
Worried, sad or unhappy	1161	1.7 (20)	1141	71.2 (812)	23.5 (268)	5.3 (61)

We will confirm with an expert group what sort of services might be relevant to ensure that data collection is as parsimonious as possible, resulting in the addition of questions in the form of days missed from school/truancy. The use of these services may have resource-use implications that can be factored into the analysis and modelling. Engagement with criminal and social services was measured in the questionnaire in the pilot study and will be collected in the definitive study.

Summary

In relation to collecting case diary data of the time spent by learning mentors on working on interventions, the open-ended format of the case diary proved to have many limitations; however, in order to identify the categories needed in a definitive trial this was important and has enabled us to identify the categories needed for the definitive trial tool (see *Appendix 6*). The revised tool should be piloted with a few learning mentors prior to beginning the definitive trial to ascertain whether it is 'user-friendly'.

The majority of young people indicated that they had no problems on the first three dimensions of the EQ-5D-Y (mobility 93%, looking after self 99%, doing usual activities 94%). Higher levels of problems were found in the dimensions of pain or discomfort (19% having some level of problems) and being worried, sad or unhappy (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. Results of this study show that the questions needed for health-economic analysis are acceptable for use with young people; however, some thought should be given to how we measure service use, especially in relation to certain categories (i.e. GP visits).

Chapter 8 Summary and conclusions

This study has successfully tested the feasibility of conducting a trial of ASBI in the school setting with young people aged 14–15 years. As there had been little research carried out in the school setting, examining a single session of one on one ASBI for young people who are drinking at a risky level, this feasibility study was imperative to trial the processes, tools and interventions, as well as the conduct of the study, including recruitment and design, and, finally, the delivery of the interventions. The previous chapters have discussed the results fully. This chapter presents the main findings relating to the study objectives and suggests modifications to the proposed definitive study (shown in *italic text*).

Objective 1

- The study succeeded in recruiting seven schools as planned. Part of this success was due to gaining the support and active involvement of the local authority in the study catchment area from the outset. The local authority provided the research team with written confirmation it was happy for the study to proceed in its geographical area, and schools were informed that the project was supported by the local authority.
- A range of factors influenced school participation in the study: the project 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.

Objective 2

- Interviews were carried out with six school lead liaisons; 13 learning mentors; 27 young people and seven parents (total $n = 53$).
- *School setting* Qualitative interviews were specifically focused on feasibility and acceptability of the intervention and not on the wider engagement of parents in a school setting. Views from school staff were mixed regarding engagement of parents in the school setting, and appeared to reflect the focus of the school. Therefore, schools that were part of the 'Extended Schools Agenda' were more likely to describe school as a 'hub' of the local community (and felt that they regularly engaged with parents) than traditional academically focused schools. Although parents felt that school was the correct environment for an intervention aimed at young people's alcohol use, they were unsure about their own involvement in school-based alcohol education, and suggested that they did not know whether their children would take them seriously if they were involved regularly in formal alcohol education, or whether other young people would always be open and honest in front of their parents. It would seem that the school is both a feasible and an acceptable environment to intervene with young people who are risky drinkers.
- *Learning mentors* Learning mentors in particular are well placed to discuss alcohol with young people due to their role within the school, their existing supportive relationships with young people and the trust that the young people place in them. Learning mentors were seen as appropriate members of staff to carry out the interventions by staff, parents and young people.
- *Training* The study showed that it was possible to train learning mentors in the research requirements (consent/intervention delivery); the length and content of training was seen as appropriate by learning mentors; learning mentors particularly liked the training manuals with which they were provided.
- *Screening* Overall, the screening survey was found to be feasible as has been found in the literature (see *Chapter 2*). Teachers were often present, overseeing the class while the young people completed the screening survey. These teachers had not been trained in best-practice approaches to this research method, however, and had received only minimal information regarding the purpose of the 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. *In the definitive study, consideration should be given to means of enhancing the young people's privacy in order to increase acceptability. Study instructions for the young people should be made clearer on the front of the questionnaire at baseline. A standardised set of instructions should be provided for each class, perhaps as a video clip produced by the research team. We believe that these changes would improve the numbers of young people leaving their names on the questionnaires.*

- 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. *In the definitive study further emphasis will be placed upon the importance of personalised feedback within the delivery of interventions. All learning mentors randomised to the intervention arm will be audio-recorded while delivering the intervention within a simulated session with an actor (see Objective 3, Fidelity) and further training will be provided to learning mentors who continue to find this aspect of the intervention challenging. As learning mentors (and young people) expressed mixed views about the calorie-focused content of the intervention, this will be removed from the intervention in the definitive trial.*
- Intervention 2 was not feasible to deliver within this study. Parents and young people did not express a desire to engage in this intervention or a benefit doing so, which has been shown in previous studies (see Chapter 2). Findings demonstrated that existing knowledge about young people's drinking was the primary factor influencing parent participation in intervention 2. Thus, if parents did not know about their drinking, young people were far less inclined to consent to a family intervention. Although parents are a source of both risk and protective factors for adolescent alcohol use, as highlighted in our rapid review, evidence that interventions for alcohol involving parents are viable is equivocal.
- Moreover, learning mentors, parents and young people questioned the utility of an intervention, which 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 young people interviewed told us that they did not want their parents involved. Furthermore, as shown in Chapter 2 and Appendix 2, the literature around parental involvement is equivocal, with no clear indication that involving parents in interventions to reduce their children's drinking is effective. *This suggests that the definitive trial should focus on working with young people rather than involving parents.*⁸³

Objective 3

- *Fidelity* In this study the BECCI index was used to measure the fidelity of the delivery of interventions by the learning mentors.¹⁷⁸ This tool is used to measure the microskills of behaviour change counselling. As such, it focuses upon the practitioner. It is not able to measure the young people's responses to the intervention or consider characteristics or compositions of the groups receiving the interventions. Six interventions were assessed. The mean score was '2.5', with a range of 1.9–3.0, which suggested that the learning mentors were all found to be delivering the behaviour change counselling aspect of the intervention to 'some extent' or to 'a good deal', as assessed with the BECCI. The rate of recorded interventions was lower than was anticipated. We acknowledge the lack of detail regarding fidelity assessment and the low number of interventions assessed. Sessions that were assessed showed that learning mentors performed well when discussing the risks associated with young people drinking alcohol. Learning mentors performed less well when discussing motivation for behaviour change and strategies for behaviour change. *The suggestion for a definitive trial is to include a minimum of one simulated intervention with an actor immediately after training for all learning mentors who are randomised to the intervention arm. A specific date to be agreed with each learning mentor for a further recording of intervention delivery with a trial participant.*

Objective 4

- Six per cent ($n = 87$) of parents opted their child out of participating in the study. Discussions with young people and parents on the days of the survey indicate that many of these parents thought they were opting their children *into* the study, which implies that the letter was confusing. Ninety-two per cent (1280/1388) of Year 10 year groups completed the baseline survey, and of these students 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, which showed willingness to be contacted later. This eligibility rate of 18% was slightly lower than we anticipated (presumed to be approximately 22%). At baseline, 40% screened positive on the study screening tool (A-SAQ), but only slightly over half of these young people left their name and so were contactable regarding participation in the pilot trial. Although young people who did not leave their names were drinking more, it is important to note that there was a considerable number who were drinking at risky levels who did leave their names. *In the definitive study, instructions should be made simpler and clearer on the letter that goes to parents, with one tick box indicating opt-out with a clear instruction that the young person will be opted out only if the box is ticked and the letter signed. The A-SAQ should be used as the screen for coming into the definitive trial, as it is short and quick to answer, with the AUDIT being asked at both baseline and 12-month follow-up.*
- *Survey* We found very low rates of missing data for virtually all variables. The highest rate of incomplete data (10%) was on the WEMWBS well-being questionnaire. This was the last set of questions in the survey pack, and it is possible that lack of time or fatigue led to more missing values. There was little evidence of implausible values being recorded, except for a few young people saying that they exercised on more than 7 days per week. There were a few very high values reported for alcohol use and problems but these could not be regarded as implausible. *For the definitive study, consideration should be given to reducing the number of questions in the survey instrument.*
- *Survey* At TP1, 50% of the sample were male and 94% were white. The prevalence of smoking rose from 20% at TP1 to 25% at TP2 and reduced to 23% at 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.
- *Survey* The proportion of young people who reported drinking alcohol fewer than four times in the last 6 months (A-SAQ) was 39% at TP1, 47% at TP2 and 47% at TP3. The proportion of young people who scored positive for an alcohol-use disorder using the AUDIT adult cut-off of 8+ rose from 26% at TP1 to 29% at TP2 to 32% at TP3. Using a cut-off of 2+, recommended for young people, this rate rose from 58% at TP1 to 66% at TP2 to 69% at TP3. The differences in all measures between TP1 and TP2 was significantly different but not between TP2 and TP3. Between the first two surveys, the median scores for AUDIT increased by two points, whereas AUDIT-C increased by one point, but there was no change in median scores between the second and third surveys. This highlights the differences in using different tools and cut-offs for identifying young people who are risky drinkers; however, all measurements show high levels of risky drinking at all three time points. The TLFB is a more robust measurement of alcohol consumption; however, it is more time-consuming to administer *therefore for the definitive study the 28-day TLFB should be used as the primary outcome measure at 12-month follow-up.*
- *Survey* The WEMWBS measures general psychological health, with a scoring range of 14–70, with a higher score indicating higher levels of mental well-being. At TP1 the median score for the WEMWBS was '48', which is comparative to other studies with young people (median 49).¹⁶¹ The RAPI was calculated only for those who reported drinking. At TP1 the median score was '2'. RAPI showed a moderate association with alcohol (using AUDIT 0.76 and AUDIT-C 0.65), whereas WEMWBS showed a very weak correlation (using AUDIT -0.13 and AUDIT-C -0.08).
- *Trial* The comparison between subgroups at baseline demonstrated that gender, smoking and sexual behaviour were significantly associated with young people's current drinking behaviour, using the AUDIT and AUDIT-C.

- *Trial* Learning mentors recruited 80% of those young people who were eligible for the pilot trial. This recruitment rate matched that which we had anticipated (approximately 79%). Very few young people did not consent to the study (10%). However, 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. *This could be seen as a form of voluntary or involuntary withdrawal from the study and would need to be taken account of in a future study.*
- *Control* Of the 60 young people eligible for the trial, three did not meet with the learning mentor (5%) and five did not give consent (8%). In total, 52 out of 60 were recruited to the trial (87%).
- *Intervention 1* Of the 79 young people eligible for the trial, 15 did not meet with the learning mentor (19%) and 10 did not give consent (13%). In total, 54 out of 79 were recruited to the trial (68%). Therefore, both the control and condition 1 arms were found to be feasible.
- *Intervention 2* Recruitment of young people to the intervention 2 arm was higher than expected. Of the 90 young people eligible for the trial, seven did not meet with the learning mentor (8%) and eight did not give consent to intervention 1 (9%). In total, 75 out of 90 were recruited to the trial and received intervention 1 (83%). However, having agreed to enter the trial, many of the young people in the intervention 2 arm did not receive the full intervention as planned. Of the 75 students recruited into this arm, 25 of these students agreed to their parents being contacted (33%); however, only eight (11% of the 75 and 32% of the 25) received both the individual intervention (intervention 1) and family intervention (intervention 2). There is more work needed to engage with parents in interventions in the school setting. *Despite the input of lots of time and resources from the school and research staff, it was not, however, possible to engage parents in the third arm of the trial, reflecting experiences in other studies.*¹⁹²
- *12-month follow-up* Once enrolled in the trial, 88% of trial participants provided data at the 12-month follow-up meeting with the learning mentor (control, 83%; intervention 1, 91%; intervention 2, 89%). This was a higher rate than we had anticipated (65%) and it reflects well on the efforts of the trial team, learning mentors and school processes. *The pilot trial has achieved the goal of demonstrating that outcome measures could successfully be collected on a high proportion of participants.*

Objective 5

- There were very low levels of missing data in the baseline survey or the EQ-5D-Y (3.4–3.9%), with the tool being seen as appropriate. The majority of young people indicated that they had no problems on the first three dimensions (mobility 93%, looking after self 99%, doing usual activities 94%). Higher levels of problems were found in the dimensions of pain or discomfort (19% having some level of problems) and being worried, sad or unhappy (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. *For the definitive study the EQ-5D-Y and service use should be assessed at baseline and 12-month follow-up. Implausible values, in relation to service use, should be reassessed, especially in the case of visits to the GP, which showed a higher-than-average percentage of 'implausible' values, and different implausible levels could be given for different service use.*
- In relation to service use, there was between 4.2% and 4.8% of answers missing at baseline. The majority of young people reported no use of services. The only possible exception was 'GP visit'. Implausible data (values of seven or more) were found in 3% of all answers at baseline.
- The use of open-format diaries meant that differing levels of data were reported by learning mentors, especially in relation to preparation time. *In the definitive study, case diaries should be made more concise and time categories should be provided. Time should be reported by ticking boxes of preselected times, informed by the summary statistics regarding the times reported in the feasibility study. Different forms will be needed for each arm of the trial. This will enable accurate data to inform an economic evaluation. These forms should be piloted with a small group of learning mentors to establish face validity.*

Objective 6

For the definitive trial, we propose a four-region, two-arm, cRCT (randomisation at school level), with integrated economic and process evaluations. This would enable generalisable results and take into account geographical, ethnic and socioeconomic differences, as well as reflecting differences in organisation of education services. The literature shows that ASBI with young people is effective and the results of this present study show that it is feasible and acceptable to intervene with young people aged 14–15 years in the school setting. The intervention with parental involvement was found not to be feasible or acceptable. The hypothesis for the definitive trial would be that ASBI is more effective and cost-effective at reducing hazardous drinking in young people (aged 14–15 years) than a control condition of screening, feedback that the young person may be drinking at a risky level and an information leaflet, as well as usual advice in Year 10 of high/comprehensive schools in England. This research will have a broader impact on both the target community (young people) and wider society in reducing health and social harms and inequalities. Primary and secondary outcome measures will be the same measures used in the pilot feasibility trial.

- *Screening tool* A lifestyle survey, as used in the present study, which includes questions relating to risky drinking.
- *Regions* North East England, North West England, Kent and South London.
- *Primary outcome measure* Reduction in alcohol use using the 28-day TLFB questionnaire¹⁹³ at 12-month follow up.
- *Secondary outcomes* Risky drinking using the A-SAQ² and AUDIT;¹⁶² smoking behaviour; alcohol-related problems using the RAPI;¹⁶³ emotional well-being using the WEMWBS;¹⁵⁹ and quality of life and health utility will be measured using the EQ-5D-Y.¹⁶⁵ A modified S-SUQ will capture health and social resource costs for the integrated economic evaluation.¹⁶⁶ Learning mentor time will be assessed using a revised case diary sheet (see *Appendix 6*).
- *Proposed design* The multicentre, two-armed cRCT, incorporates a control and intervention condition. Schools will be paid £1000 for taking part in the research study for the time involved. Young people will not be given a £5.00 gift voucher, as in the pilot study, for two reasons: (1) it would be very costly and (2) this would not happen if the study was mainstreamed.
- *Screening* All pupils in Year 10 (aged 14–15 years) in each of the schools, whose parents have not opted them out of the study, will be asked to complete a voluntary questionnaire that will contain a number of tools including the primary and secondary outcome measure tools. All young people who screen positive and leave their name will be asked to consent to the trial by the learning mentor.
- *Control condition* Standard alcohol advice delivered in PSHE lessons delivered by class teachers, feedback to the young person that they are drinking in a way that may be harmful, and provision of an advice leaflet by the learning mentor.
- *Intervention 1* In addition to PSHE, the young people who are eligible (risky drinkers) and consent to participate will be given feedback that they are drinking in a way that may be harmful and provided with an advice leaflet. They will then take part in a 30-minute personalised interactive worksheet-based session, developed during the pilot feasibility trial. This will be delivered by the learning mentor (at school) and consist of structured feedback about their drinking behaviour and advice about the health and social consequences of continued hazardous alcohol consumption. The intervention encompasses the elements of the FRAMES approach for eliciting behaviour change (Feedback, Responsibility, Advice, Menu, Empathy and Self-efficacy).⁵⁹
- *12-month follow-up* All young people who come into the trial will be invited to meet with the learning mentor 12 months post intervention, during which they will be asked to complete the same battery of questionnaires used at baseline, as well as the 28-day TLFB.

- *Training* All learning mentors will receive school-based training in the study procedures and the intervention that is relevant to their school. Learning mentors will be brought together at one of the schools in each geographical area for this training. Such outreach training was found to be the most cost-effective implementation strategy for ASBI delivery in the pilot² and in other settings.¹⁵⁶ Intervention training for learning mentors will be carried out by an experienced trainer. Learning mentors will be provided with support materials and will be assessed as competent by the trainer prior to embarking on the study. Changes to the training and manual will take into account learning from the pilot feasibility trial. Ongoing support and supervision will be provided by clinical staff working on the project.
- *Fidelity* We will carry out a minimum of one audio-recorded intervention delivered per learning mentor within the intervention arm of the trial.
- *Setting* High/comprehensive schools are governed by the local authorities in England. Screening will take place in the PSHE or registration class on a classroom basis. Interventions will take place in the learning mentor's classroom or office space. This will be the anticipated setting for roll-out if the project is implemented.
- *Patient and public involvement participation* PPI has been imperative to the success of the pilot feasibility trial and this will be continued in the main trial with involvement from young people and parents; however, we acknowledge that more in-depth PPI work is needed in the definitive trial. We intend to set up a management group to steer the research in each of the schools that take part in the study, which will include teaching staff/learning mentors and young people. Views from these groups will feed into the PMG on a regular basis.
- *Qualitative work* Semistructured in-depth interviews will be carried out in each of the schools with staff and young people. The interviews will further explore factors that potentially hinder or enhance the use of ASBI approaches in the school setting and with the target age group, with the aim of exploring future roll-out of such work.
- *Sample size* As a two-arm trial, 100 responses would be needed per arm with individual randomisation and a significance level of 5%. We intend to use minimisation to balance out both school size and percentage free school meals. Using other trial parameters as above, this would equate to 220 young people per arm, and a total of 18 schools (nine per arm) when clustering is taken into account.

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Study governance references

Study full title	A pilot feasibility 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)	
Study short title	SIPS JR-HIGH	
Trial sponsor	Newcastle University	
Trial funder	NIHR Public Health Research programme	10/3002/07
Trial registration	International Standard Randomised Controlled Trials Register	ISRCTN07073105
Ethical approval	Newcastle University	00508/2011

Contributions of authors

All authors read and agreed the final draft report.

Dorothy Newbury-Birch (Lecturer in Public Health Research, project management) was the Chief Investigator on the study and took overall responsibility for the study and the writing of the report.

Stephanie Scott (née O'Neil) (Research Associate and SIPS JR-HIGH Project Manager) project managed the study and co-drafted the report.

Amy O'Donnell (Research Assistant, qualitative research) co-analysed and co-drafted the qualitative chapter of the final report.

Simon Coulton (Professor of Health Services Research, health services research) contributed to the design of the study, conduct of the trial and the PMG.

Denise Howel (Senior Lecturer, statistics) contributed to the design of the study, conduct of the trial and PMG, supervised the statistical component of the research, carried out statistical analysis, and co-drafted the survey and trial chapters.

Elaine McColl (Professor of Health Services Research and Director of the Newcastle Clinical Trials Unit, methodology) contributed to the design of the study, conduct of the trial and PMG.

Elaine Stamp (Research Associate, statistics) carried out the statistical analysis of the study and co-drafted the survey and trial chapters.

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Appendix 1 Terms of reference for Programme Management Group and Trial Steering Group

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

Terms of reference for the Programme Management Group

These terms of reference will guide the scientific, administrative and operational direction of the SIPS JR-HIGH feasibility trial.

Chief Investigator Dr Dorothy Newbury-Birch, Institute of Health & Society, Newcastle University

Aims and objectives

The PMG has the primary aim of ensuring appropriate, effective and timely implementation of the SIPS JR-HIGH trial.

The PMG will strive to achieve this aim by fulfilling the following objectives:

- identify appropriate sites for conducting the SIPS JR-HIGH trial
- participate in the development and compilation of data collection instruments and other relevant research and intervention manuals
- determine tasks, schedules and deliverables of the SIPS JR-HIGH trial
- determine the appropriateness of trial interventions
- produce a working protocol for the trial and ensure adherence to the protocol
- develop a publication protocol
- facilitate and support the preparation of the ethics application
- facilitate and support data analysis
- determine tasks, schedules and deliverables for report writing and publication of findings
- develop incentives for schools and young people to take part in the trial
- develop a definitive trial application
- ensure that adequate supervision/support occurs for research staff.

Membership Eilish Gilvarry (Chair); Dorothy Newbury-Birch (Chief Investigator); Eileen Kaner; Simon Coulton; Elaine McColl; Chris Speed; Denise Howel; Elaine Stamp; Mark Deverill; Erin Graybill; Les Tate; Colin Drummond; Paolo Deluca; Paul McArdle; Stephanie Scott.

Membership of the group will be reviewed as appropriate and as required.

Meeting The PMG will meet once a month or more often if needed. Members are able to join the meeting by teleconferencing. A meeting will be considered quorate when at least three members are in attendance.

Reporting The group will report to the TSG, chaired by Professor Mark Bellis.

Duration The group will function for the entire duration of the SIPS JR-HIGH trial.

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

Terms of reference for the Trial Steering Group

These terms of reference will guide the scientific, administrative and operational direction of the SIPS JR-HIGH feasibility trial.

Chief Investigator: Dr Dorothy Newbury-Birch, Institute of Health & Society, Newcastle University

Aims and objectives

The TSG has the primary aims of monitoring implementation of the SIPS JR-HIGH feasibility trial, providing an independent assessment of the data analysis and determining if a future trial is merited.

The TSG has the following objectives:

- provide overall supervision of the trial on behalf of the trial sponsor and funder and ensure it is conducted to rigorous standards
- comment on the progress of the trial and adherence to protocol
- consider new information of relevance to the research question
- provide advice, through the Chair, to the Chief Investigator and trial funder on all appropriate aspects of the trial
- provide evidence to support any requests for extensions.

Meeting The TSG will meet biannually. Members are able to join the meeting by teleconferencing. A meeting will be considered quorate when at least three members are in attendance. Dorothy Newbury-Birch and Stephanie Scott will be responsible for calling, organising and minuting the meeting.

Duration The group will function for the entire duration of the SIPS JR-HIGH feasibility trial.

Membership:

Name	Position
Professor Mark Bellis (Chair)	Director, Centre for Public Health and North West Public Health Observatory
Ms Catherine Gillespie	Vice Principal
Miss Rebecca Leighton – Year One	Young Mayor
Mr Isaac Sidney – Year Two	
Ms Anne Taylor	Young Mayors' support worker and mother of adolescents
Georgia Hall and Louise Burn	Young person and her mother
Dr Gillian Lancaster	Director of the Postgraduate Statistics Centre
Membership of the PMG: Dorothy Newbury-Birch (Chief Investigator); Stephanie Scott (Research Associate and Project Manager); Denise Howel (Statistician). Other members of the PMG as necessary	

Membership of the group will be reviewed as appropriate and as required.

Appendix 2 Literature review table

TABLE 21 Literature review

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Azrin <i>et al.</i> (1994) ¹⁰⁷	USA (counselling centre)	RCT	Illegal drug users; mean age 27.5 years; 68% male; n = 82	Non-behavioural treatment (n = 36)	Behavioural treatment (n = 46)	12-month drug use data, including urinalysis	Subjects using drugs in the non-behavioural group decreased to 80% in first month and remained at that general level for remaining 11 months In the behavioural treatment group, subject users decreased progressively to 35% at 12 months. Chi-squared tests at each month showed that the difference between the two treatments was statistically significant for each month after the second month ($p < 0.05$); 12th month, $\chi^2 = 13.097$ (1, $n = 82$) ($p < 0.001$)	77
^a Azrin <i>et al.</i> (2001) ¹⁴⁹	USA (Youth Justice)	RCT	Dually diagnosed drug and alcohol users; mean age 15.4 years; n = 56; 82% male	No control	Individual cognitive problem-solving therapy 15 sessions (60–90 minutes) or family behavioural therapy x 15 sessions (60–90 minutes)	TLFB	An analysis of alcohol use results indicated no within-subject or between-intervention group differences ($p > 0.05$), indicating that both interventions had no significant effects on the no. of days these young people used alcohol. Both interventions were found to reduce illicit drugs and conduct disorder (no between-group differences)	None

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Baer <i>et al.</i> (2001) ⁸⁷	USA (university)	RCT	High-risk drinkers, 45% male Normative comparison sample, 46% male Age – students <19 years in autumn of 1990	No intervention	Individualised feedback	Baseline interview and questionnaires then yearly follow-up questionnaires for 4 years	Findings suggest that much heavy drinking among college students is transitory. Compared with the high-risk control sample, participants receiving brief individual preventative intervention had significantly greater reductions in negative consequences over the 4-year period	78
Baer <i>et al.</i> (2007) ¹⁰⁸	USA (homeless young people)	RCT	Mild to moderate substance abusers; mean age 17.9 years; 56% male	Usual care (n = 52)	Brief MI (≤4 sessions of 60 minutes) (n = 75)	30-day TLFB	Per-protocol analysis showed there were significant reductions in alcohol use at 3- but not 1-month follow-up assessments (Cohen's <i>d</i> = 0.20)	75, 77
Bailey <i>et al.</i> (2004) ⁵³	Australia (youth centre)	RCT	Not restricted to substance users; mean age 15.4 years; 50% male	Usual care but they had fortnightly access to an alcohol or drug counsellor (n = 17)	Brief MI and cognitive/behavioural-based group programme [four sessions (≤10 people) of 30 minutes]	AUDIT	Participants in the intervention group reduced their frequency of drinking at the first follow-up assessment, whereas the control group reported increases at the second follow-up assessment (p < 0.005). The control group also increased their hazardous drinking (p < 0.005) and frequency of binge drinking compared with the intervention group (p < 0.005)	38, 74, 75, 78
continued								

TABLE 21 Literature review (continued)

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Battjes <i>et al.</i> (2004) ¹²¹	USA (outpatient substance abuse treatment programme)	Group evaluation (no control)	Mild to moderate substance abusers; mean age 15.9 years; 85% male	No control	Group-based treatment for adolescent substance abuse (19 weekly group sessions of 75 minutes with limited individual and family therapy) (n = 194)	Days of alcohol intoxication in previous 90 days	No statistically significant differences were found with regard to days of alcohol intoxication in past 90 days	75
Bernstein <i>et al.</i> (2009) ⁹⁵	USA (emergency department)	Prospective three-group RCT (preliminary)	Marijuana users (excluded if high-risk alcohol use); 71% ≥ 18 years; 37% male	Standard assessed control (n = 71) and non-assessed control (feasibility)	Screening and BI by trained peer educators, including CRAFFT test (n = 68)	TLFB calendar	Small pilot study. There was increased marijuana abstinence and reduced consumption in patients aged 14–21 years. Strongest effects seen at 12-month follow-up (OR 2.89). No differences in risk behaviours or health consequences from baseline to follow-up	76
Bernstein <i>et al.</i> (2010) ⁹⁸	USA (emergency department)	Three-group randomised assignment trial	Patients aged 14–21 years giving positive AUDIT test or positive for binge drinking/high-risk behaviours; 87% ≥ 18 years; 45% male	Assessed control (n = 284) and minimally assessed control (n = 286)	Peer-conducted MI, referral to community resources and treatment if indicated and 10-day booster in addition to assessment (n = 283)	30-day TLFB	No effects were found for between-group consumption or high-risk behaviours. Intervention compared with AC resulted in significant efforts to change behaviour (p < 0.05)	76, 79

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Boekeloo et al. (2004) ⁸⁰	USA (primary care)	RCT	12- to 17-year-old adolescents receiving general health examination; 40% male	Usual care (n = 150)	<i>Intervention 1:</i> 15-minute audio programme (n = 150) <i>Intervention 2:</i> 15-minute audio programme and prompts from primary care provider (n = 147)	Adolescent alcohol beliefs at exit interview and self-reported behaviours at follow-ups	No evidence to suggest BI reduces alcohol intake. At 1-year follow-up, both intervention groups reported more bingeing in the last 3 months than the control group (OR 3.44 and 2.86). Intervention 1 reported more drinking in the last 30 days (OR 2.31) and in the last 3 months (OR 1.76) than the control group	38, 78
Borsari and Carey (2000) ⁸⁸	USA (college)	RCT	Student binge drinkers; mean age 18 years; 43% male	No treatment (n = 31)	One session of motivational intervention (n = 29)	Drinks consumed per week, number of times consuming in past month, frequency of binge drinking in last month and RAPI scores	At 6-week follow-up, the BI group showed significant reductions on number of drinks consumed per week, number of times drinking alcohol in past month and frequency of binge drinking in past month	78
Borsari and Carey (2005) ⁸⁹	USA (college)	RCT (two groups)	Students referred for alcohol violation with score of ≥ 10 on AUDIT and 2+ binge-drinking episodes in past 30 days; mean age 19 years; 83% male		<i>Intervention 1:</i> Brief MI (no info.) (n = 34) <i>Intervention 2:</i> Advice given but not personalised (no info.) (n = 30)	AUDIT and typical blood alcohol content	Both intervention groups decreased their alcohol use following the intervention; however, brief MI students reduced alcohol-related problems to a greater extent	78

continued

TABLE 21 Literature review (continued)

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Carey <i>et al.</i> (2006) ⁹⁰	USA (university)	RCT	Heavy drinking students; mean age 19 years; 35% male	No intervention	<i>Intervention 1:</i> Basic MI – advice (one session of 65 minutes) <i>Intervention 2:</i> Enhanced MI including a decisional balance exercise (one session of 70 minutes)	Drinks per typical week and drinks per drinking day: Daily Drinking Questionnaire	TLFB reduced consumption but not problems at 1 month relative to control subjects. Basic MI improved all drinking outcomes beyond the effects of the TLFB at 1 month, whereas the enhanced MI did not	78
Dawes <i>et al.</i> (2005) ⁹⁴	USA (community treatment centre)	Prospective, open-label trial	Adolescents with DSM-IV alcohol dependence; mean age 18 years; 58% male	No control	Eight-week, prospective, open-label ondansetron (Zofran, GlaxoSmithKline) (4 µg/kg b.i.d) treatment and weekly CBT (n = 12)	Safety and tolerability of drug. Self-reported alcohol consumption	Six out of 12 participants completed 8-week study. Adverse events were mild and of short duration. Very small sample but intention-to-treat analysis showed significant within-group decreases (improvement) for drinks/drinking day ($p = 0.01$)	73
D'Amico <i>et al.</i> (2008) ⁹¹	USA (primary care clinic)	RCT	High-risk drug and alcohol users; age 12–18 years; male 48%	Usual care (n = 24)	Project CHAT: MI (one session of 15–20 minutes; 5–10 minute booster call) (n = 36)	CRAFT	No statistically significant differences were found with regard to alcohol consumption	38, 74–77

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Esposito-Smythers <i>et al.</i> (2006) ¹⁹⁵	USA (adolescent psychiatric inpatient unit)	Pilot study	Adolescents with co-occurring alcohol use disorder and suicide ideation; mean age 15 years; five females; one male	No control	Six-month acute treatment phase, 3-month maintenance phase and 3-month booster phase administered by study therapists (n = 6)	Treatment feasibility/acceptability. Changes in suicidality, alcohol and marijuana use	Pilot suggests that outpatient CBT is feasible and acceptable to families. Retention was good: five out of six families completed 12-month treatment. Few obstacles were reported. All five participants reported reductions in suicidal ideation. However, two of five made a suicide attempt and were referred back to the treatment. All participants reported a reduction in number of drinking days, heavy drinking days and days of cannabis use	73
Feldstein and Forcenhimes (2007) ⁹¹	USA (university)	RCT	Included participants need to report drinking at least once in the past month and have either a RAPI score of at least '3' or at least one bingeing episode in past 2 weeks; mean age 18.6 years; 21.8% male	No treatment (n = 19)	One-session MI (n = 36)	Binge-drinking question and RAPI	Multivariate tests reveal no significant interaction effects	78

continued

TABLE 21 Literature review (continued)

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Friedman <i>et al.</i> (2002) ¹⁰⁹	USA (residential facility for court-adjudicated males)	RCT	New court-adjudicated admissions to residential treatment centre who were not ineligible; mean age 15.5 years; 100% male	Control subjects (no treatment) (n = 91)	Botvin LifeSkills Training (20 sessions), PSAV (20 sessions), Values Clarification procedure (20 sessions) – all 55 minutes each (n = 110)	ADAD scores at follow-up	The Botvin LifeSkills Training programme was effective in reducing substance use/abuse and the selling of drugs. Participants who participated more positively in the PSAV programme reduced their violent behaviour at follow-up to a significantly greater degree	74, 77
Godley <i>et al.</i> (2002) ¹¹⁰	USA (residential treatment system for alcohol or other substance-use disorders)	RCT	Adolescents with alcohol and/or marijuana dependence; age range 12–18 years; 76.3% male	UCC (n = 51)	UCC plus an ACC protocol (n = 63)	Baseline and follow-up interviews using GAIN and Form 90 version of TLFB	ACC participants were significantly more likely to initiate and receive more continuing care services, to be abstinent from marijuana at 3 months post discharge, and to reduce their 3-month post-discharge days of alcohol use Preliminary findings suggest that ACC can increase linkage and retention in continuing care and improve short-term substance-use outcomes	77

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Godley <i>et al.</i> (2007) ¹¹¹	USA (residential treatment facility)	RCT	Current alcohol and/or other drug dependence (DSM-IV); mean age 16.2 years; 71% male	UCC (n = 81)	ACC (UCC plus 90-day case manager assigned) (n = 102)	GAIN instrument, service contact logs and General Continuing Care Adherence scale	At follow-up, ACC participants were more likely to link to continuing care services (94% vs. 54%; $p < 0.001$) ACC group had significantly longer-term abstinence from marijuana. Superior early abstinence outcomes for both conditions predicted longer-term abstinence	77
Grenard <i>et al.</i> (2007) ⁹⁹	USA (alternative high schools)	RCT	Mean age 16.1 years; male 67%	Usual care (n = 7)	MI session (one session of 25 minutes) (n = 11)	Prevalence of alcohol use in past 30 days and lifetime	Small numbers to follow up therefore no statistical difference between groups	74–76
^a Henggeler <i>et al.</i> (1999) ¹¹²	USA (Youth Justice)	RCT	Drug and alcohol users; mean age 15.7 years; 79% male	Usual services (referral to probation officer for substance abuse services)	Multisystemic therapy within the home (n = 58) (mean no. of 130 days with a mean of 40 hours' direct contact and 26 indirect contacts of a mean of 15 minutes each). Control group, usual services (n = 60)	Personal experiences inventory	The multisystemic therapy group showed significantly less alcohol and marijuana use than usual services shortly after treatment [$F(1, 112) = 5.40$; $p < 0.022$]; however, this effect was not evident at 6-month follow-up	77

continued

TABLE 21 Literature review (continued)

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Johnston (2002) ⁹⁶	USA (emergency department)	RCT	Adolescents in emergency department undergoing treatment for injury; mean age 16.4 years; 65.2% male	Routine emergency department care (n = 312)	Brief session of behavioural change counselling (n = 317)	Prevalence of positive behaviour change and interim occurrence of medically treated injuries	The intervention was associated with a greater likelihood of positive behaviour change in seatbelt and bicycle helmet use. Behaviour change counselling was not associated with changes in other risk behaviours and could not be shown to significantly reduce the risk of reinjury	76, 79
Kaminer and Burleson (1999) ¹¹³	USA (outpatient aftercare following inpatient treatment)	Pilot	Met DSM-III-R criteria for psychoactive substance use disorders; age range 13–18 years; 62.5% males	No control	<i>Intervention 1:</i> CBT (n = 17) <i>Intervention 2:</i> Interactional treatment (n = 15)	Teen-addiction severity index, teen treatment services review and SCQ	Small sample size. No effects at 3-month follow-up. At 15 months there was no differential improvement as a function of therapy type	77
Kaminer et al. (2008) ¹¹⁴	USA (outpatient setting)	RCT	Current DSM-IV diagnosis of AUD, n = 144; mean age 16 years, range 13–18 years; 80% male	NA	<i>Intervention 1:</i> Five-session in-person aftercare <i>Intervention 2:</i> Five-session brief telephone aftercare	Diagnostic Interview Scale for Children (DISC-IV) at baseline. Urinalysis for marijuana status. Alcohol use, ACQ questionnaire	The likelihood of relapse increased significantly at end of aftercare compared with end-of-treatment outcomes. Likelihood of relapse in young people in 'No active aftercare' (NA); however, increased significantly more for young people in combined active aftercare (in-person and brief telephone aftercare) conditions (p = 0.008). 'Active aftercare' also showed significantly fewer drinking days (p = 0.044) and fewer heavy drinking days (p = 0.035) per month relative to NA	77

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Kemp <i>et al.</i> (2007) ⁹⁶	Australia (Community)	RCT	Young people with primary diagnosis of psychotic illness and substance abuse; age range 17–25 years; <i>n</i> = 17; 81% male	TAU (<i>n</i> = 6)	SUS intervention comprising four to six brief MI-CBT-based sessions	PANSS, DAST-10, AUDIT, Depression Anxiety Subscale (DASS), SES, WHO Quality of Life Scale	Both the SUS and TAU participants showed improvements in alcohol use [<i>F</i> (1, 14) = 4.718; <i>p</i> < 0.05] and substance use [<i>F</i> (1, 14) = 7.0; <i>p</i> > 0.05] The SUS group exhibited a greater reduction in substance and alcohol use than the TAU group	73
^a Latimer (2003), ¹¹⁵ USA	USA (drug dependence assessment clinic)	RCT	Drug and alcohol users; mean age 16 years; 77% male	NA	Drugs Harm Psychoeducation Curriculum 16 x 90-minute group sessions (<i>n</i> = 22) Integrated Family and CBT 16 x 60 minutes family therapy sessions and 32 x 90 minutes CBT group sessions (<i>n</i> = 22)	Diagnostic interview	Drugs Harm Psychoeducation Curriculum group used alcohol 6.06 days (SD 7.15) significantly more than Integrated Family and CBT = 2.03 days (SD = 2.49) (effect size 0.56) at 6-month follow-up	77
^a Liddle <i>et al.</i> (2008), ¹¹⁷ USA	USA (community drug treatment clinic)	RCT	Drug and alcohol users; mean age 15 years; 81% male; 72% African American	NA	Individual CBT weekly session for 4–6 months (<i>n</i> = 112) Multidimensional Family Therapy weekly session for 4–6 months (<i>n</i> = 112)	TLFB	Although there were significant results favouring Multidimensional Family Therapy for drug use and severity, this was not found for alcohol use. Both treatment groups showed reduction in alcohol use however, this was not significant and no significant between group differences were found (12-month follow-up)	77

continued

TABLE 21 Literature review (continued)

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Liddle <i>et al.</i> (2001) ¹¹⁶	USA (clinical outpatients)	RCT	Marijuana and alcohol abusing adolescents; mean age 15.9 years; range 13–18 years; <i>n</i> = 182; 80% male	No control	Three interventions: Multidimensional Family Therapy (<i>n</i> = 47), Adolescent Group Therapy (<i>n</i> = 53), and Multifamily Educational Intervention (<i>n</i> = 52). 14–16 weekly sessions	Adolescent Drug Use Scale, Acting Out Behaviours Scale	All three interventions showed improvements in drug use and acting out behaviours across time, with the greatest improvements seen in the Multidimensional Family Therapy group	77
Liddle <i>et al.</i> (2009) ¹⁹⁷	USA (community drug abuse treatment agency)	RCT	Referred for outpatient treatment of substance abuse problem; mean age 13.7 years, range 11–15 years; 74% male	No control	Two interventions: Multidimensional Family Therapy (<i>n</i> = 40), Peer Group Therapy (<i>n</i> = 43). Both had 2 x sessions per week, 90 minutes' duration for 12–16 weeks	GAIN, POSIT, National Youth Survey SRD	Both interventions were effective in reducing substance use. Latent growth curve modelling analyses demonstrated superior effectiveness of Multidimensional Family Therapy over the 12-month follow-up in reducing substance use (effect size: substance use frequency, <i>d</i> = 0.77; substance use problems, <i>d</i> = 0.74). Multidimensional Family Therapy also had improved delinquency, family, and school outcomes whereas the peer group therapy did not	73

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Maio <i>et al.</i> (2005) ⁸²	USA (emergency department)	RCT	Young people attending the emergency department with minor injury; mean age 15.9 years; range 14–18 years; <i>n</i> = 580; 66% male	No intervention (<i>n</i> = 285)	Laptop-based interactive programme based on social learning theory completed in the emergency department setting (<i>n</i> = 295). Average completion time = 25 minutes	Alcohol misuse index, binge-drinking episodes	The emergency department-based interactive computer program to limit adolescent alcohol misuse had no significant effect at 3- or 12-month follow-up. Subgroup analysis suggested that there may be a benefit among those participants admitting to drinking and driving at baseline	38, 76, 78, 79
Marlatt <i>et al.</i> (1998) ⁹²	USA (university)	RCT	High-risk sample selected from screening pool (<i>n</i> = 348)	Normative sample from screening pool (<i>n</i> = 115) and assessment only, control (<i>n</i> = 174)	Individualised MI (<i>n</i> = 174)	Frequency of alcohol consumption, daily drinking questionnaire, RAPI, alcohol dependence scale	All high-risk participants drank less and reported fewer drinking-related problems over a 2-year follow-up period. Participants who received the BI showed significantly greater deceleration of drinking rates and problems over time than the control group	78
Marsden <i>et al.</i> (2006) ¹⁰⁰	UK (community agency)	RCT	Self-report users of MDMA (ecstasy), cocaine powder or crack cocaine; age range 16–22 years; <i>n</i> = 342	Control – standard written health risk information (<i>n</i> = 176, 154 analysed)	Stimulant- and alcohol-based brief MI. One session, 45–60 minutes plus standard written health risk information (<i>n</i> = 166, 145 analysed)	MAP, AUDIT	There were no significant differences in abstinence for ecstasy, cocaine powder or crack cocaine use between the experimental and control groups. Contrasting follow-up with baseline self-reports, there were no between-group effects for changes in the frequency or amount of stimulant or alcohol use	75, 76

continued

TABLE 21 Literature review (continued)

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Mason and Posner (2009) ²²	USA (medical centres)	Matched group	Cannabis and alcohol users; mean age 16 years; male 81%	NA	Individual motivational enhancement therapy (two sessions of 60 minutes) then group CBT (three sessions 60–75 minutes)	Global appraisal of individual needs	A significant reduction in number of days of alcohol use in treatment group in past 30 days at 3 months ($p=0.001$) and 6 months ($p=0.02$)	75
McCambridge et al. (2004, 2005) ^{102,106}	UK (further educational colleges)	Cluster RCT	Drug use in previous 3 months; age 16–20 years; male 75%	Usual care ($n=105$)	Brief MI (one session of 60 minutes) ($n=105$)	Severity of Dependence scale	At baseline both groups were drinking a mean of 12.7 units per week. A reduction of 5.71 units was found in the intervention group at 3-month follow-up ($p=0.0002$). For drinkers only at baseline, there was a reduction of 6.89 units in the intervention group at 3 months	75, 76
McCambridge et al. (2008) ¹⁰¹	UK (further education colleges)	RCT	Cannabis users; age 16–20 years	Usual care ($n=164$)	Brief MI (one session of 60 minutes) ($n=162$)	AUDIT	No statistical differences were found for any of the alcohol outcomes at 3 or 6 months post intervention	75, 76
^a McGillicuddy et al. (2001), USA ¹¹⁸	USA (community sample)	RCT	Alcohol and drug users; mean age 16.3 years; 73% male	Waiting list ($n=8$)	Skill training programme for parents (8 x weekly 2-hour sessions) ($n=14$)	TLFB (parent report)	No effects detected for alcohol	77
Monti (1999) ⁸⁴	USA (emergency department)	RCT	Emergency department users following alcohol-related incident; age range 18–19 years; $n=94$	Standard care ($n=42$)	Brief MI (one session of 35–40 minutes) ($n=52$)	Alcohol Drinking Index, Young Adult Drinking and Driving Questionnaire, Health Behaviour Questionnaire	Patients who received MI had significantly lower incidence of drinking and driving, traffic violations, alcohol-related injuries and alcohol-related problems than patients who received standard care, 6 months following intervention	38, 78, 79

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Monti <i>et al.</i> (2007) ⁸³	USA (emergency department)	RCT	Alcohol users; age range 18–24 years; <i>n</i> = 198; 68% male	Personalised feedback only; booster sessions at 1 and 3 months (<i>n</i> = 100, 86 analysed)	Brief MI with personalised feedback (one session of 30–45 minutes), telephone booster sessions at 1 month (20 minutes) and 3 months (25–30 minutes) (<i>n</i> = 98, 79 analysed)	BAC, AUDIT, RAPI	Six months after the intervention MI participants drank on fewer days, had fewer heavy drinking days and drank fewer drinks per week in the past month than did feedback-only patients. These effects were maintained at 12 months. Clinical significance evaluation indicated that twice as many MI participants as feedback-only participants reliably reduced their volume of alcohol consumption from baseline to 12 months	38, 78, 79
Murphy <i>et al.</i> (2001) ⁸⁴	USA (university)	RCT	Alcohol users, upper 33% of screening sample; <i>n</i> = 84; 54% female	(<i>n</i> = 25)	Two intervention groups: BASICS 50-minute MI session (<i>n</i> = 30), or an educational intervention, 50-minute session with 30 minutes for video and general discussion (<i>n</i> = 29)	Alcohol Dependence Scale, Daily Drinking Questionnaire, RAPI	No overall significant group differences were seen at 3- or 9-month follow-up	78
Peterson <i>et al.</i> (2006) ⁸⁶	USA (homeless drop-in centres and street intercept)	RCT	One binge-drinking episode in past 30 days; mean age 17.4 years, range 14–19 years; <i>n</i> = 285; 55% male	Two control groups – assessment only (<i>n</i> = 99) and assessment at follow-up (<i>n</i> = 94)	Brief Motivational Enhancement (1 session of 30 minutes) (<i>n</i> = 92)	Self-report alcohol and drug use frequency – past 30 days	No treatment effects were found with respect to alcohol	38, 73–76

continued

TABLE 21 Literature review (continued)

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Santisteban <i>et al.</i> (2003) ¹¹⁹	USA (Hispanic families)	RCT	126 Hispanic families with adolescent exhibiting externalising behaviour problems (substance use not required); mean age 15.6 years, range 12–18 years; 75% male	Group treatment – adolescents received 6–16 weekly sessions, of 90 minutes' duration (n = 46)	Brief strategic family therapy – families received 4–20 1-hour sessions depending on clinical severity of presenting problems (n = 80)	Revised Behaviour Problem Checklist, Addiction Severity Index, Family Environment Scale, Structural Family Systems Rating	Substance use (alcohol and marijuana) change scores between intake and termination were statistically significant [Wilks' $\lambda = 0.89$, $F(2, 68) = 4.33$; $p < 0.02$, $\eta^2 = 0.11$] A significant univariate effect emerged for marijuana use, but not for alcohol use	77
^a Slesnick <i>et al.</i> (2006) USA ¹⁹⁸	USA (runaway shelter)	Analysis data from two RCTs	Primary alcohol users, n = 123 primary drug users; mean age 15.0 years; 56% female	TAU, n = 101	Ecological-based family therapy-mean of 10 sessions (SD = 6) (n = 101)	CDISC Form 90	Primary alcohol users showed clinically and statistically significant reductions in frequency of alcohol use (from 28% days to 1% days of use = 97% reduction) when assigned to ecological-based family therapy compared with TAU (from 25% of days to 6% days = 76% reductions) at 15-month follow-up. However, alcohol use increased by 32% for primary drug users receiving family therapy (from 3.3% of days to 4.8%)	73

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Slesnick <i>et al.</i> (2007) ¹⁹⁹	USA (homeless)	RCT	Homeless young people engaged with drop-in centre; met DSM-IV criteria for substance use disorder; mean age 19.1 years, range 14–22 years; n = 180; 66% male	TAU through a drop-in centre (n = 84). Case management sessions available at young people's request – mean 3.4 sessions attended	Community reinforcement approach (n = 96); 12 sessions – mean attendance 6.8 sessions	Form 90, POSIT, NYSDS, YSR, CISS, BDI-II, Health Risk Questionnaire	Overall, both the community reinforcement approach and the TAU groups showed improvements over time. Young people assigned to community reinforcement approach compared with TAU reported significantly reduced substance use (37% vs. 17% reduction), depression (40% vs. 23%) and increased social stability (58% vs. 13%)	73
Spirito <i>et al.</i> (2004) ⁸⁵	USA (emergency department)	RCT	Treated in emergency department and had evidence of alcohol use (blood/breath/saliva) or self-report consumption within 6 hours of admittance; mean age 15.7 years; n = 152; 64% male	Standard care – 5 minutes' brief advice and handout (n = 74)	Brief MI (one session of 35–45 minutes) (n = 78)	Adolescent drinking questionnaire, adolescent drinking inventory, young adult drinking and driving questionnaire, adolescent injury checklist, adolescent health behaviour questionnaire	Both MI and standard care conditions resulted in reduced quantity of drinking during the 12-month follow-up. Adolescents who screened positive for problematic alcohol use at baseline reported significantly more improvement on two out of three alcohol-use outcomes (average number of drinking days per month and frequency of high-volume drinking) if they received MI compared with standard care	38, 74–76, 78, 79

continued

TABLE 21 Literature review (continued)

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
^a Spirito <i>et al.</i> (2011) ¹⁰³ USA	USA (emergency department)	RCT	Drug and alcohol users; 54% female; mean age = 15.45 years		IMI session for 45–60 minutes and 5-monthly parenting booster brochures (n = 63) As above with the addition of family check-up (n = 62)	Adolescent drinking questionnaire	Both conditions resulted in a reduction in all drinking outcomes at 3-, 6- and 12-month follow-up (p = 0.001). Across groups any drinking in previous month decreased from 100% to 39.3% at 3 month, 55.2% at 6 months and 67.9% at 12 months. High-volume drinking occurrence dropped from 84% at baseline to 24% at 3-month follow-up, 35.3% at 6 months and 53.3% at 12 months; all were significantly less than baseline (p < 0.001). There was one significant between-group difference on high-volume drinking days at 3 months with family check-up reporting lower prevalence (14.6%; 95% CI 3.8% to 25.5%) compared with individual IMI (32.1%, 95% CI 19.9% to 44.4%), at 6 months. Family check-up was lower (27%; 95% CI 12.7% to 41.3%) than IMI (43.6%, 95% CI 30.5–56.8%). No difference was shown at 12 months. There were no effects on number of drinking days or quantity per drinking occasion.	76

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Stein <i>et al.</i> (2006) ¹²⁴	USA (juvenile correctional facility)	RCT	Alcohol and/or marijuana users; mean age 17.1 years, range 14–19 years; <i>n</i> = 105; 90% male	NA	1 x MI session of 60 minutes; booster of 90 minutes (<i>n</i> = 59) or relaxation training (<i>n</i> = 45)	DSM-IV, Centre for Epidemiological Studies – Depression scale, Risky Behaviours Questionnaire – driving under influence and passenger with driver under influence	Lower rates of those in the 'Driving under the influence' and 'Passenger with driver under the influence' groups' risky behaviours were seen with the MI intervention compared with the relaxation training intervention. Effects were moderated by depression; those with low levels of depression receiving MI had the lowest rate of risky behaviours	73, 74
Thush <i>et al.</i> (2007) ⁹⁴	Netherlands (school)	RCT	Mean age 15.5 years; range 14–18 years; <i>n</i> = 107; 57% male	Information-only control (<i>n</i> = 54)	'Learning to Drink'; 7 x weekly session (6 x 90-minute group sessions, 1 x MI) plus 1 x parent session	Alcohol use questionnaires; RAPI	The intervention was effective in changing several of the targeted cognitive determinants: there was a significant increase in the perception of risk factors for developing alcohol-related problems and a significant decrease in positive alcohol expectancies for a high dose of alcohol in the experimental group compared with the control group. However, no long-term effects of the intervention on drinking behaviour were found (measured at 1 month, 6 months and 12 months)	78
continued								

TABLE 21 Literature review (continued)

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Thush (2009) ¹²³	Netherlands (low-level vocational schools)	RCT	Mean age 17.1 years, range 15–23 years; n = 125 (n = 110 in analysis); 54% female	Information-only control – received 5 x information leaflets (n = 64, 55 analysis)	1 x MI session lasting 30 minutes; 5 x information leaflets (n = 61, 55 analysis)	Alcohol use questionnaire, RAPI	There were no differential effects of the MI intervention on drinking behaviour or readiness to change at 1- and 6-month follow-up	75
Tomlinson et al. (2004) ¹²⁰	USA (outpatient aftercare following inpatient treatment)	RCT	Adolescents with comorbid substance use disorders and Axis I psychiatric disorder; age range 13–17 years; n = 126	Substance use disorders only, control group; n = 81	Subjects admitted to one of five inpatient adolescent treatment programmes: all were abstinence focused, offered individual and group CBT and used 12-step model of treatment	Structured clinical interview of adolescents' substance abuse history, DSM-IV	Results indicated that comorbid young people received more treatment during the outcome period. However, more comorbid SUD-Axis I disordered adolescents used substances following treatment than substance-use disorders only young people. Among comorbid young people, internalising disordered adolescents were less likely to use substances during the follow-up period, and externalising disordered young people returned to substance use most rapidly after discharge from treatment	77

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
^a Valdez <i>et al.</i> (2013) ¹⁴⁸	USA (gang-affiliated Mexican American adolescents)	RCT	Range of risk behaviours exhibited; mean age 15.25 years; 59% male	Referral to social and behavioural services and substance abuse counselling (n = 104)	Brief strategic family therapy x 16 sessions plus four additional educational sessions (n = 96)	30-day calendar-based tool	Significant differences were found between control and brief strategic family therapy groups re. alcohol at 6 months' follow-up showing a steady and significant decline over time. Brief strategic family therapy group reported significantly fewer days of alcohol use (m = 1.23, SD.79) number of days compared with control (m = 4.05, SD.74) number of days during last 30 days at 6 months (p = 0.05)	None
Walker <i>et al.</i> (2006) ¹⁰⁴	USA (school)	RCT	Marijuana users; mean age 15.8 years, range 14–19 years; n = 97	Delayed feedback control	Motivational enhancement therapy (2x session with health educator, 30–60 minutes)	GAIN-I	Both the motivational enhancement therapy and delayed feedback control groups significantly reduced marijuana use at the 3-month follow-up (p < 0.001); no between-group differences were observed	76

continued

TABLE 21 Literature review (continued)

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
Walton <i>et al.</i> (2010) ⁹⁷	USA (emergency department)	RCT	Eligible if reported past-year alcohol use and aggression; mean age 16.8 years, range 14–18 years; <i>n</i> = 726, 56% female	Control group received brochure post screening (<i>n</i> = 235)	SafERteens therapist (<i>n</i> = 254) vs. computer BI (one session of 35 minutes) (<i>n</i> = 237)	AUDIT, AUDIT-C, POSIT, frequency of aggression towards peers	At 3 months, the therapist intervention showed reductions in the occurrence of peer aggression (therapist –34.3%; control –16.4%; relative risk 0.74; 95% CI 0.61–0.90); experience of peer violence (therapist –10.4%; control –4.7%; relative risk 0.70; 95% CI 0.52 to 0.95); and violence consequences (therapist –30.4%; control –13.0%; relative risk 0.76; 95% CI 0.64 to 0.90). At 6 months, both the therapist intervention and computer intervention showed reductions in alcohol consequences compared with controls (therapist –32.2%; control –17.7%; OR 0.56; 95% CI 0.34 to 0.91; computer –29.1%; control –17.7%; OR 0.57; 95% CI 0.34 to 0.95)	74, 76, 79

Author (year)	Country (setting)	Methodology	Participants	Control	Intervention (n)	Measures	Outcomes	Referenced in systematic review
^a Winters and Leitten (2007) ¹⁰⁵	USA (school)	RCT	Alcohol and drug users; mean age 15.6 years; 62% male	Assessment only (control) (n = 27)	Two sessions of adolescent BI x 60 minutes (n = 26) Two sessions of 60 minutes BI-adolescent plus BI-parent session (n = 126)	Adolescent Diagnostic Interview and TLFB	There was a significant group by time effect at 6-month follow-up, BI with parent showing significantly lower no. of alcohol use days and no. of binge days than the control, the BI-adolescent group had significantly lower scores on the no. of alcohol use days than the control, whereas the BI-parent had significantly lower no. of alcohol days than the BI-adolescent group	76, 77
^a Winters <i>et al.</i> (2012) ¹²⁵	USA (school)	RCT	Adolescents with alcohol/drug use disorder; mean age 16 years; range 12–18 years; n = 315; 52% male	Assessment only (control) (n = 56)	Two sessions of BI-adolescent x 60 minutes (n = 135) Two sessions x 60 minutes BI-adolescent plus BI-parent session (n = 123)	Adolescent Diagnostic Interview and TLFB	Both intervention groups (BI-adolescent and BI-parent) showed significantly better outcomes than control ($p < 0.05$) for no. of alcohol use days, no. of alcohol abuse symptoms and no. of alcohol dependency symptoms. BI-adolescent was found to be significantly better than BI-parent for no. of days abstinent from alcohol in past 90 days	74

AC, assessed control; ACQ, Alcohol Consumption Questionnaire; ADAD, Alcohol and Drug Abuse Division; ACC, assertive continuing care; BAC, blood alcohol concentration; BASICS, Brief Alcohol Screening and Intervention for College Students; BDI-II, Beck Depression Inventory version II; b.i.d., twice a day; CDISC, Clinical Diagnostic Interview Schedule for Children; CISS, Coping Inventory for Stressful Situations; DASS, Depression Anxiety Subscale; DAST, Drug Abuse Screening Test; DISC-IV, Diagnostic Interview Schedule for Children; DSM-III-R, Diagnostic and Statistical Manual of Mental Disorders version III, Revised; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition; GAIN, Global Appraisal of Individual Needs; GAIN-I, Global Appraisal of Individual Needs – Initial version; MAP, Maudsley Addiction Profile; MDMA, 3,4-methylenedioxy-N-methylamphetamine; NA, no active aftercare; NYSDS, National Youth Survey Delinquency Scale; OR, odds ratio; PANSS, Positive and Negative Symptom Scale; POSIT, Problem Orientated Screening Instrument for Teenagers; PSAT, Prothrow-Stith Anti-Violence Model; SCQ, Situational Confidence Questionnaire; SRD, Self-Report Delinquency Scale; SUD, substance use disorder; SUS, 'Stop Using Stuff'; TAU, treatment as usual; UCC, usual continued care; WHO, World Health Organization; YSR, youth self-report.

^a Parental involvement in intervention.

Appendix 3 Study documentation and manual

Parent opt-out letter

Institute of
Health&Society



Institute of Health and Society

Newcastle University

Baddiley-Clark Building

Richardson Road

Newcastle Upon Tyne

9 November 2011

Dear Parent,

I am writing to you about a research study that is being carried out by Newcastle University and your child's High School. The study is investigating whether young people would benefit from receiving advice during school time about their drinking behaviour. The researchers are trying to find out whether this advice may help with reducing the harm caused by alcohol to young people.

During this study all pupils in Year 10 will be asked to complete a written questionnaire and may be invited to take part in a subsequent advice session about alcohol during school time. The questionnaire will explore smoking, sexual health and general attitudes towards health in addition to alcohol use.

Please find enclosed a copy of the Participant Information Sheet, which provides further details about the study, as well as contact details for the research team if you would like further information. Please read this carefully and take time to consider if you would like your child to take part in the study. You may like to discuss taking part with family or friends before you make up your mind.

If you would like your child to take part in the study, then you don't need to take any action. The research team will be working with the school to arrange a time for the research to be carried out.

If you would prefer your child **not to** take part in this study or be contacted by the study team, please return the attached 'opt-out' slip in the stamped addressed envelope provided within two weeks of the date of this letter. You will not be contacted about this study again.

Yours Sincerely

A handwritten signature in black ink, appearing to read 'D Birch'.

Dr Dorothy Newbury-Birch

SIPS JR-HIGH



Parental Consent Form



*To be completed by a parent or guardian who **DOES NOT AGREE** to their child taking part in the SIPS JR-HIGH Young People and Alcohol study at their child's school.*

Please
Tick
Box

Name of Researchers: Stephanie O'Neil and Dr Dorothy Newbury-Birch

1. I confirm that I have read and understand the participant information leaflet dated 10/08/2011 (version 1) for the above study and have had the opportunity to ask questions. ☐
2. I **DO NOT** wish my child to take part in the above study ☐

Please use BLOCK CAPITALS

Your name

Child's full name

Child's school

Signature of parent / guardian

Date

Study information leaflet



Research Information Leaflet Version 1 18.10.11

Thank You...

Who is funding and organising the study?
The study is funded by the National Institute for Health Research (NIHR) and sponsored by Newcastle University.

What happens to the results of the study?

We're happy to send you a report at the end of the project if you're interested. The study will be printed in academic journals and presented at conferences. You will not be identified in any of the information written about the study.

Will the research help me?

We can't promise that this study will help you directly. However, the study may give you the chance to talk openly about alcohol. The information that you give will be used to help understand the decisions you and other young people make.

For further information and advice about your drinking...

- Talk to Frank: [redacted]
- Speak to Drinkline: [redacted]
- For local support, contact Never 2 Late (N2L), North Tyneside on [redacted]

for taking the time to read this leaflet. Please ask your teacher or Learning Mentor to answer any questions or concerns you may have about the project. If you decide to take part, please keep this leaflet for future reference.

Any suggestions and complaints about the study or how you were treated will be dealt with, in writing, within 7 working days. They should be made in writing to Dr Dorothy Newbury-Birch at the address below.



Dr. Dorothy Newbury Birch
Alcohol Research
Programme Manager



Stephanie O'Neil
Research Associate

Institute of Health & Society, Newcastle University
Baddiley-Clark Building, Richardson Road,
Newcastle upon Tyne, NE2 4AX
Telephone: [redacted]

SIPS JR-high

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What is this study about?

You are being invited to take part in a research study about alcohol. This leaflet is for you to keep. Please read it carefully and take time to decide if you want to take part or not. Talk to other people about the study if you want to. Please ask us if there is anything that you don't understand or that you would like more information on.

What will happen to me if I take part?*The Questionnaire*

We want to understand more about alcohol use among people your age. During school time your class will be asked to fill out a questionnaire. **The questionnaire will explore smoking, sexual health and general attitudes to health as well as alcohol use.**

You can choose not to complete the questionnaire; to complete it anonymously or with full contact details. There are no right or wrong answers. Your answers will not be passed on to parents or teachers.

You will be asked to place your completed questionnaire in a blank envelope and seal it yourself. Sealed questionnaires will be collected by the research team.

You will receive a compensatory £5.00 gift voucher after completing the questionnaire.

We will return to your school and ask your class to complete an additional questionnaire about alcohol in 6 and 12 months time.

The Study

We also want to find out whether young people would benefit from receiving advice during school time about their drinking behavior.

After completing a questionnaire you may be invited to receive advice about changing your drinking behavior, delivered by staff at your school.

Completing a questionnaire does not mean that you have to take part in the rest of the study.

Advice may consist of a leaflet; a 30 minute personalized session; or an extended one hour session (to which parents will be asked to attend). The type of advice you receive will be chosen at random by the research team.

Do I have to take part?

It's up to you to decide.

We will describe the study, go through this information sheet with you and answer your questions. If you decide to take part in the study, you'll be asked to sign a consent form.

You're free to change your mind at any time; you will not need to give a reason. If you do decide not to take part in the study, any information you give will be destroyed.

Who will have access to my information?

All information collected about you during this research will be kept confidential. The only people who will be able to look at it will be the research team at the University.

All information will be stored on a password protected computer. Data will be kept for 10 years within the University according to the rules of the Data Protection Act. After 10 years, the data will be destroyed securely.

Data from school records may be looked at by members of the research team only if it is relevant to this research.

Researchers work to the same rules of confidentiality as doctors and nurses which can only be broken, without your consent, in very exceptional circumstances. **Usually this is if the researcher sees or is told something which raises serious concern for your personal safety.**

Could I be at risk by taking part?

We're confident that you will not experience any harm as a result of taking part in this research study. However, if it is proven that you are harmed during the research, and this is because of the researcher's lack of care, you may have grounds for legal action against Newcastle University. You may have to pay your own legal costs.

Screening questionnaire

SIPS JR-high

Baseline Questionnaire

Before you start, please read this

We want to understand more about alcohol use among students your age. Your class has been randomly selected to take part in this study. You are one of about 1400 young people in the area participating in the study.

This is a confidential questionnaire – only the research team will have access to the responses you provide. Your answers will not be passed on to parents or teachers.

When you have finished the questionnaire, please put it in the enclosed envelope and seal it yourself. Your teacher / survey administrator will collect the envelopes after completion.

If the study is to be successful, it is important that you answer each question as thoughtfully and frankly as possible. Remember, your answers are totally confidential.

The study is completely voluntary. You can choose not to complete the questionnaire; to complete it without giving your name or with full contact details. If there is any question which you object to for any reason please just leave it blank.

This is not a test. There are no right or wrong answers. If you do not find the answer that fits exactly, mark the one that comes closest. Please mark the appropriate answer to each question by making an 'X' in the box.

We hope that you find the questionnaire interesting. If you do have a question, please raise your hand and your teacher / survey administrator will assist you.

Thank you in advance for your participation.



OFFICE USE ONLY

ID Number:

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Before beginning the questionnaire, we'd like to know a little bit of background information about you.

Date questionnaire completed:

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Name:	
School:	
Class:	
PSHE Teachers name:	

OFFICE USE ONLY							
ID Number: <table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>							

**Before beginning the questionnaire please be sure to read the instructions on the cover.
Please mark your answer to each question by marking an 'X' in the appropriate box.**

**The first questions ask for some extra information about you and about how you
spend your free time.**

1. Are you? Male: ☐ Female: ☐

2. What is your Ethnic group?

White	<input type="checkbox"/>	Asian	<input type="checkbox"/>
Black	<input type="checkbox"/>	Other	<input type="checkbox"/>
Chinese	<input type="checkbox"/>	Not known	<input type="checkbox"/>
Mixed	<input type="checkbox"/>		

3. When you have free time do you mainly:

Go round to a friend's house (or have them come round to yours)	<input type="checkbox"/>
Go out somewhere with friends	<input type="checkbox"/>
Spend time with your family	<input type="checkbox"/>
Spend time with brothers(s) and/or sister(s)	<input type="checkbox"/>
Spend time by yourself	<input type="checkbox"/>
None of these	<input type="checkbox"/>

The following questions ask about diet and physical activity. *Physical activity* is any activity that increases your heart rate and makes you get out of breath some of the time, such as running, brisk walking, dancing, skateboarding, biking, swimming, netball, football and rugby

4. Over the past seven days, on how many days were you physically active for a total of at least 60 minutes per day?

<input type="text"/>	<input type="text"/>
----------------------	----------------------

5. Over a typical or usual week, on how many days are you physically active for a total of at least 60 minutes per day?

--	--

6. How many pieces of fruit, of any sort, do you eat on a typical day?

--	--

7. How many portions of vegetables, excluding potatoes, do you eat on a typical day?

--	--

The following questions are about CIGARETTE SMOKING.

8. How old were you when you smoked a whole cigarette for the first time?

I have never smoked a whole cigarette

8 years old or younger

9 or 10 years old

11 or 12 years old

13 or 14 years old

Over 14 years old

9. During the past 30 days, on the days you smoked, how many cigarettes did you smoke per day?

I did not smoke cigarettes during the past 30 days

Less than 1 cigarette per day

1 cigarette per day

2 to 5 cigarettes per day

6 to 10 cigarettes per day

11 to 20 cigarettes per day

More than 20 cigarettes per day

The following questions are about **ALCOHOL**.

10. The following questions ask about the alcohol you have drunk in the **last 6 months**. The questions ask about how many standard drinks (units) you have consumed. A description of a standard drink is given in the box below. So, for example, a pint of regular beer or lager is equal to 2.5 standard drinks.



In the last 6 months how often have you drunk more than 3 units of alcohol?

Never	Less than 4 times	4 or more times but not every month	At least once a month but not every week	Every week but not every day	Every day
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

How often do you have a drink containing alcohol?

Never	Monthly or less	2 to 4 times a month	2 to 3 times a week	≥4 times a week
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

How many standard drinks containing alcohol do you drink on a typical day when you are drinking?

1 to 2	3 to 4	5 to 6	7 to 9	10 or more
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

How often have you had 6 or more standard drinks if female, or 8 or more if male, on a single occasion in the last 6 months?

Never Less than monthly Monthly Weekly Daily or almost daily

How often during the last 6 months have you found that you were not able to stop drinking once you had started?

Never Less than monthly Monthly Weekly Daily or almost daily

How often in the last 6 months have you failed to do what was normally expected of you because of your drinking?

Never Less than monthly Monthly Weekly Daily or almost daily

How often in the last 6 months have you needed an alcoholic drink in the morning to get you going?

Never Less than monthly Monthly Weekly Daily or almost daily

How often in the last 6 months have you had a feeling of guilt or regret after drinking?

Never Less than monthly Monthly Weekly Daily or almost daily

How often in the last 6 months have you not been able to remember what happened when drinking the night before?

Never Less than monthly Monthly Weekly Daily or almost daily

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------	----------------------

Have you or someone else been injured as a result of your drinking?

No Yes but not in the last year Yes, during the last year

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

Has a relative/friend/doctor/health worker been concerned about your drinking or advised you to cut down?

No Yes, but not in the last year Yes, during the last year

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

11. Different things happen to people while they are drinking alcohol or because of their alcohol drinking. Indicate how many times each of these things happened to you within the last 6 months (circle the relevant number for each question).

1-2 3-5 5+
None times times times

0 1 2 3 Not able to do your homework or study for a test

0 1 2 3 Got into fights with other people (friends, relatives, strangers)

0 1 2 3 Missed out on other things because you spent too much money on alcohol

0 1 2 3 Went to work or school high or drunk

0 1 2 3 Caused shame or embarrassment to someone

0	1	2	3	Neglected your responsibilities
0	1	2	3	Relatives avoided you
0	1	2	3	Felt that you needed <u>more</u> alcohol than you used to in order to get the same effect
0	1	2	3	Tried to control your drinking (tried to drink only at certain times of the day or in certain places, that is, tried to change your pattern of drinking)
0	1	2	3	Had withdrawal symptoms, that is, felt sick because you stopped or cut down on drinking
0	1	2	3	Noticed a change in your personality
0	1	2	3	Felt that you had a problem with alcohol
0	1	2	3	Missed a day (or part of a day) of school or work
0	1	2	3	Wanted to stop drinking but couldn't
0	1	2	3	Suddenly found yourself in a place that you couldn't remember getting to
0	1	2	3	Passed out or fainted suddenly
0	1	2	3	Had a fight, argument or bad feeling with a friend
0	1	2	3	Had a fight, argument or bad feeling with a family member
0	1	2	3	Kept drinking when you promised yourself not to
0	1	2	3	Felt you were going crazy

0 1 2 3 Had a bad time

0 1 2 3 Felt physically or psychologically dependent on alcohol

0 1 2 3 Was told by a friend, neighbour or relative to stop or cut down drinking

The following questions ask about SEXUAL BEHAVIOUR

12. After drinking alcohol, have you ever engaged in sexual intercourse that you regretted the next day?

I have never engaged in sexual intercourse

Yes

No

13. After drinking alcohol, have you ever engaged in sexual intercourse without a condom?

I have never engaged in sexual intercourse

Yes

No

14. This section asks about your use of health and social resources in the past 6 months. Please read each question carefully and remember each question relates to the past 6 months only. If your answer is none, please enter zero ('0') in the box.

In the past 6 months how many times have you visited the school nurse?

In the past 6 months how many times have you visited an accident and emergency department as a patient?

In the past 6 months how many times have you been admitted to hospital?

In the past 6 months how many times have you visited a doctor at your GP practice?

In the past 6 months how many times have you visited or been visited by a social worker at home?

In the past 6 months how many times have you been arrested?

15. The following questions are about your health TODAY. Under each heading, mark ONE box that best describes your health TODAY

Mobility (walking about)

☐ I have no problems walking about

☐ I have some problems walking about

☐ I have a lot of problems walking about

Looking after myself

☐ I have no problems washing or dressing myself

☐ I have some problems washing or dressing myself

☐ I have a lot of problems washing or dressing myself

Doing usual activities (eg. Going to school, hobbies, sports, playing, doing things with family or friends)

☐ I have no problems doing my usual activities

☐ I have some problems doing my usual activities

☐ I have a lot of problems doing my usual activities

Having pain or discomfort

☐ I have no pain or discomfort

☐ I have some pain or discomfort

☐ I have a lot of pain or discomfort

Feeling worried, sad or unhappy

☐ I am not worried, sad or unhappy

☐ I am a bit worried, sad or unhappy

☐ I am very worried, sad or unhappy

16. Below are some statements about feelings and thoughts. Please tick the box that best describes your experience of each over THE LAST TWO WEEKS.

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future	1	2	3	4	5
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been feeling interested in other people	1	2	3	4	5
I've had energy to spare	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling good about myself	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been feeling confident	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5
I've been feeling loved	1	2	3	4	5
I've been interested in new things	1	2	3	4	5
I've been feeling cheerful	1	2	3	4	5

Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)

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Thank you for completing this questionnaire

Please remember to collect your leaflet and gift voucher

SIPS JR-high



Study manual*Full intervention manual*

SIPS JR-high



Study Manual

Contacts



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Chief Investigator



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Research Associate



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Preparation and Support

a. Prior to the Intervention

This training pack contains a list of young people from your school identified as 'potential cases' for this research project as a result of their alcohol screening questionnaire result.

You have been given a separate pack for each young person identified. This pack will contain all of the resources and information that you will need in order to deliver the intervention.

Within each of the packs is a case-diary sheet where you should record any interactions to do with the relevant young person (see below). Every time you attempt or do have contact with the young person (or their family members) should be recorded on this document – this is important as it will enable to look at how long is spent arranging and carrying out the interventions.

b. During the Intervention

The researcher will organise regular meetings or school visits to answer questions or concerns; collect completed interventions; and chase up outstanding interventions. You can contact the research team at any time with any questions or concerns.

c. Date management and storage

All data relating to the study must be kept confidential. After every interaction with the young person it is important to make sure that documentation is kept in secure locked cabinets.

A member of the research team will visit the school at least once per week to collect any finalised documentation

Case Diary:

SIPS JR-HIGH: Case Diary

Name of Young Person: _____

Name of LM: _____ School: _____

Case ID (Office Use Only): _____

Please use this sheet to record all of the time you spend organising meetings or interacting with the young person. You can also use this sheet to note down anything that you find interesting and any observations that you make.

Date		Time Spent

Confidentiality and Consent

All information collected about young people in this study must be kept strictly confidential. It is anticipated that this is no different from the standards expected in your day-to-day role. Researchers work to the same rules of confidentiality as doctors or nurses. In other words, confidentiality can only be broken, without a young person's consent, in very exceptional circumstances. **Usually this is if you see or are told something which raises serious concern for a young person's personal safety.** More information is available at www.education.gov.uk/publicationDetail/Page1/DCSF-00305-2010 (eg section 2.72)



It is important that each young person is placed in full control about whether they participate in the study. The young person is also free to change their mind at any point, and they do not have to give a reason for this. **If a young person does decide that they no longer want to take part it is important to inform the researchers as soon as possible.**

At the beginning of the 1:1 appointment, the young person should be informed about why they have been asked to attend, and provided with an information leaflet about the SIPS JR-HIGH research study. Please make sure that the young person is given time to read this leaflet and ask questions.

Written and informed consent must be sought prior to delivering the intervention using the consent form provided to you by the research team (see below). **Without a completed consent form, information from any participant cannot be reported.**

This form must be signed and dated by the young person (and a separate one for each of the family members) and learning mentor; and a copy provided to the young person (and each participant) for their records. The original copy needs to be filed securely at the University and will be collected from learning mentors by the researcher.

Participant consent form (control and intervention 1)

Participant Consent Form

Please read each of the following statements and tick the box if you agree with the statement. If you have ticked all of the boxes please sign and date the form.



	Please Tick Box
1. I confirm that I have read the participant information leaflet dated 21/10/2011 (version 2) for the above study.	<input type="checkbox"/>
2. I confirm that I have had the opportunity to ask any questions about the study and any questions I have asked have been answered to my satisfaction.	<input type="checkbox"/>
3. I understand that taking part is voluntary and that I'm free to change my mind at any time without giving any reason and without my education, services from school and legal rights being affected.	<input type="checkbox"/>
4. I understand that data from my school records may be looked at by members of the research team if it is relevant to my taking part in this research.	<input type="checkbox"/>
5. I understand that any data created from this study will be held in a locked filing cabinet for ten years after which the data will be destroyed. All data collected will be anonymous and kept confidential, and only members of the research team will have access to this data.	<input type="checkbox"/>
6. <i>I agree to take part in the above study. I am aware that a copy of this consent form will be provided to me for my records.</i>	<input type="checkbox"/>

Name of Participant	Date	Signature

Name of Witness	Date	Signature

Participant Consent Form Version 2 21/10/2011

Participant consent form (Intervention 2)

Participant Consent Form

Please read each of the following statements and tick the box if you agree with the statement. If you have ticked all of the boxes please sign and date the form.

<p>1. I confirm that I have read the participant information leaflet dated 21/10/2011 (version 2) for the above study.</p> <p>2. I confirm that I have had the opportunity to ask any questions about the study and any questions I have asked have been answered to my satisfaction.</p> <p>3. I understand that taking part is voluntary and that I'm free to change my mind at any time without giving any reason and without my education, services from school and legal rights being affected.</p> <p>4. I understand that data from my school records may be looked at by members of the research team if it is relevant to my taking part in this research.</p> <p>5. I understand that my parents may be invited to attend an additional session about alcohol with a school learning mentor and members of the research team.</p> <p>6. I understand that any data created from this study will be held in a locked filing cabinet for ten years after which the data will be destroyed. All data collected will be anonymous and kept confidential, and only members of the research team will have access to this data.</p> <p>7. <i>I agree to take part in the above study. I am aware that a copy of this consent form will be provided to me for my records.</i></p>	<p>Please Tick Box</p> <div style="margin-top: 10px;"><input type="checkbox"/></div> <div style="margin-top: 10px;"><input type="checkbox"/></div> <div style="margin-top: 10px;"><input type="checkbox"/></div> <div style="margin-top: 10px;"><input type="checkbox"/></div> <div style="margin-top: 10px;"><input type="checkbox"/></div> <div style="margin-top: 10px;"><input type="checkbox"/></div> <div style="margin-top: 10px;"><input type="checkbox"/></div>
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Name of Participant	Date	Signature
Name of Witness	Date	Signature

Participant Consent Form Version 2 21/10/2011

Control condition

CONTROL CONDITION

Issuing the Alcohol Information Leaflet

Introduce the control condition:

'Thank you for coming to see me. You may remember answering some questions about alcohol in class recently. The answers you gave suggested that you may be drinking alcohol in a way which may be harmful to you. Whatever we talk about will stay between you and me unless you tell me something that may place you or someone else at serious risk of harm. Here is a leaflet explaining what taking part in the project will mean. Let's read it together and I will answer any questions. If you are happy to take part, we will read, sign and date a form together, which you can have a copy of to keep'

All young people need to be provided with this leaflet (see below).

It is important that, when providing the alcohol advice leaflet, you do not provide advice or education to the young person beyond what is delivered as part of the school curriculum. Remember, we will be comparing different ways of providing young people with advice about alcohol against those who are only receiving the alcohol advice leaflet.

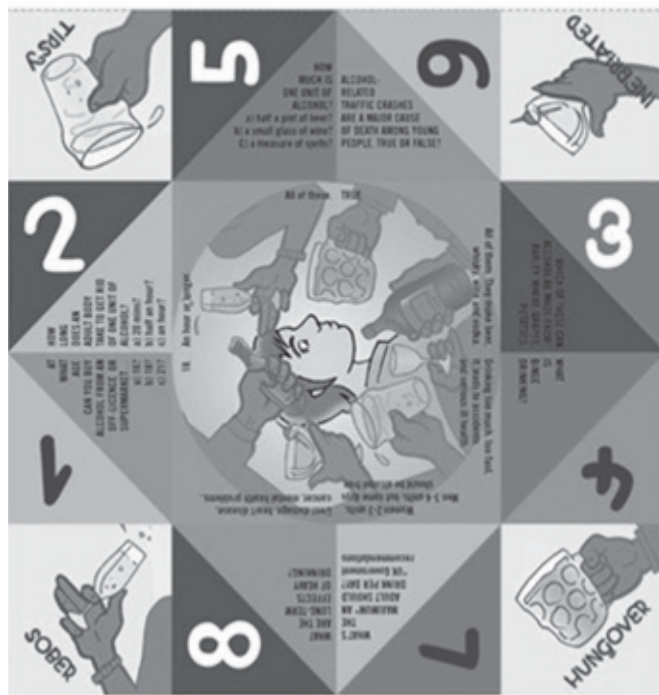
Providing the alcohol information leaflet needs to be a very short interaction, such as the following:

'Thank you for taking part in the project. These leaflets will provide you with some advice about alcohol and risks. Please take time to read the leaflet. We are also giving you some contact details if you would like any further help or advice'

At the end of the appointment, young people should be informed that (i) their class will be asked to fill in a similar questionnaire in 6 and 12 months time; (ii) they will be asked to attend a session with a learning mentor in 12 months time to fill out an additional questionnaire, which should take no longer than 20 minutes; and (iii) they may be invited to take part in an interview with a member of the research team exploring their views on the research project.

No further information needs to be discussed and the young person should be thanked again and the session completed.

Alcohol information leaflet



For confidential information and advice about alcohol

- Speak to your GP or someone you trust
- Talk to Frank: www.talktofrank.com
- Speak to Drinkline: 0800 917 8282
- Ask Brook: 0808 802 1234; www.brook.org.uk
- Call Never 2 Late (N2L): 0191 643 8802



INTERVENTION

1

Principles of Brief Intervention

Express Empathy

- An important part of brief intervention is that it is provided in a non-judgemental manner. You need to appear understanding of the participants. This allows the participant to feel comfortable to explore ideas and beliefs towards their drinking and behaviour change.
- Part of this is avoiding 'labelling language' such as good, bad, alcohol dependant.

Build a strong rapport

- Effective ways of building a rapport with your participant are through empathy, supportive listening and open body language. Remember your body language can give away a lot; keep it calm and open and relaxed.
- Ensure the room and environment (privacy, presentation, etc.) promotes engagement.
- Good rapport is essential to understanding and constructive discussion. A positive relationship can be the biggest indicator of a successful outcome.
- Understand that both you and the participant will have preconceptions/ expectations about this process. This can work against you if they see you as an authority figure... but it could also be used to your benefit because of your skills and position in the school, your opinion is more likely to be valued.

Respect is essential

- A participant's own belief and confidence that they can change is an important motivator to success. You need to be supportive of the participant's ability to change.
- Respect that a participant's decision not to change is normal and that they are an expert in their own life.

If you push you will get resistance

- This process aims to be non-threatening and non-confrontational – we are not telling the participant they should change or they have to change we are giving them information so they can make better decisions.
- Don't challenge resistance or try and direct the participant in a particular direction. Use non-confrontational language to motivate them.
- Studies have shown that the more confrontational a practitioner is the less positive the outcomes of the session. By being confrontational you are causing the participant to voice and further identify with their justifications for their current behaviour.

Actively encourage the person to voice the benefits of behaviour change

- Giving the participant opportunities to make behaviour change statements and reinforcing these through summarising and reflective listening is a crucial aspect of the Brief Intervention process.

People must decide for themselves to change

- It is most beneficial to assist the participant to come to a decision to make a change using the above methods. Decisions to change through coercion or advice are not as successful as decisions that come directly from the participant.

You or the intervention has not failed if the participant does not agree to change

- Raising doubt in a person is a positive outcome: they may go away and make a decision on their own.

INTERVENTION 1

Delivering the Brief Intervention and Providing the Alcohol Advice Leaflet

Delivering the Brief Intervention and the Alcohol Information Leaflet will take up to 30 minutes. **The start and end time of the session should be recorded in the box provided on the intervention tool.** The aim of the session is to give young people an opportunity to consider their drinking, and recognise their own motivations for reducing their alcohol consumption and the associated risks.

The session will be structured around a 6-step tool (overleaf). This A3-sized, interactive document is designed to promote a conversation between yourself and the young person about alcohol.

Introduce the 30-minute Brief Intervention:

'Thank you for coming to see me. You may remember answering some questions about alcohol in class recently. The answers you gave suggested that you may be drinking alcohol in a way which may be harmful to you. The aim of us talking today is to give you the chance to think about your drinking. Whatever we talk about will stay between you and me unless you tell me something that may place you or someone else at serious risk of harm. Here is a leaflet explaining what taking part in the project will mean. Let's read it together and I will answer any questions. If you are happy to take part, we will read, sign and date a form together, which you can have a copy of to keep'

Show the young person the Brief Intervention sheet and explain that you'll go through it with them. Young people should be encouraged to write their own answers to the questions onto the A3 sheet but its okay for you to as well.

ts 1 pint of Fosters = 2.3 units...1 440ml can of Strongbow = 2.6 units...1 330ml bottle of Stella = 2 units

1. How many units are in my drink?

Beer	Koppar Glass	1 pint	275ml	of wine	175ml	12%	4.4%	5%
Cider	Bottle of	500ml	5.2%	Cheap wine	500ml	11.5%	14%	20%
Shot	25ml	40%	Shot	35ml	40%	Shot	25ml	40%

1 275ml bottle of WKD = 1.5 units... 1 440ml can of Stella = 2.2 units... 1 440ml can of Carling = 1.8 units

2. I drink:

With:

Where:

Because:

3. I feel at risk when...

4. What do I think about my drinking?

Good:

Bad:

What do other people think about my drinking?

Good:

Bad:

5. What do I think about reducing my drinking?

Bad:

Good:

6. What could I do about my drinking?

a.

b.

c.

1 pint of Fosters = 2.3 units... 1 440ml can of Strongbow = 2.6 units... 1 330ml bottle of Stella = 2 units

1 litre bottle of Bellabrusco = 5 units... 1 litre bottle of Frosty Jacks = 7.5 units... 1 litre bottle of Strongbow = 6 units... 1 pint of Carlsberg = 3 units

Step 1: 'How many units are in my drink?'

During step 1, young people should be asked to talk about what they typically drink. To help you and the young person work out how many units of alcohol they drink on a day when they drink, there is a picture on the sheet which shows the amount of units in common drinks. The unit content of other common branded drinks is also illustrated around the border of the sheet. Help the young person to calculate how many units they drink and ask them to write this on the sheet.

It is important that you do not respond either positively or negatively to the young person's answer. A neutral response will make the young person feel safe to begin to explore and share their thoughts about their drinking with you.

'Tell me about what you drink on a typical drinking day, so I can understand what happens?'

It is recommended that young people under the age of 15 years do not drink alcohol at all. This is stated on the sheet. The recommended UK drinking guidelines for adults are also illustrated on the sheet. Conversation can be prompted by comparing the young person's drinking with both of these guidelines. As an additional discussion prompt, calorie comparisons with various food products are also included on the intervention sheet. Ask the young person what they think about their levels of drinking compared to these recommendations. You can also help the young person to work out the calorie content of the alcohol they are drinking and what the equivalent is in terms of food.

Both adults and young people are influenced by the behaviour of others. People are less likely to change their behaviour if they believe their behaviour is 'normal' and similar to that of others. Conversely, believing that the social norm is to behave in a different way promotes the likelihood of change. Ask the young person:

*'What percentage of young people aged 14 years have **never** drank alcohol?'*

Ask the young person

'What percentage of young people aged 14 years had not drunk alcohol in the last month?'

These statistics are detailed on the brief intervention sheet. Advise the young person what the actual percentages are (40% of 14 years olds have never drank alcohol; 85% of 14 year olds have not drunk alcohol in the past month). Ask the young person what they think about this.

Step 2: 'Typical drinking day'

Step 2 offers an opportunity to find out more about the context of the young person's drinking. Listen to the young person, encourage and prompt them to paint the picture.

The step is divided into 3 parts (*with, where, because*). Allow the young person to cover each of these prompts in turn; sit back and relax – don't respond to problems by giving your opinions or trying to fix them.

Summarise the main points; move on to Step 3. Ideally, Step 2 should lead naturally into Step 3, where the young person will be asked to reflect on times and situations which may make them feel at 'risk' when drinking.

Step 3: 'Are there any risks with my drinking?'

Step 3 provides an opportunity to explore the aspects of drinking discussed in Step 2 which make the young person feel at 'risk'. Remember that risk is subjective and will mean different things to different young people in different situations. Allow the young person to identify these for them self. If the young person cannot think of any risks you may wish to prompt. Use the answers from step 2 to help you do this (e.g. if young people drink in a public place there are likely to be different risks than if they drink in the house under their parent's supervision). Go through the risks of drinking above the recommended amounts with a young person. As an aid, the negatives of drinking (i.e. bad for health, weight gain, spots, hangovers, impact on relationships etc) are provided on the sheet. Ask the young person what they think about these risks to prompt further the risks in their own drinking.

Be aware that responses provided by young people in Step 3 could be useful in steps 4, 5 and 6.

Summarise the main points; move on to Step 4.

Step 4: 'How important is changing my drinking?'

This step asks the young person to consider the importance of changing their drinking. The purpose of this section is to encourage the young person to explore their motivations for change and potential for positive development of motivation. Start by asking the young person:

'On a scale of 0-10, where 0 is not important at all and 10 is very important, where would you place yourself with regards to how important it is for you to change your drinking?'

A numerical response alone does not provide any insight into the young person's motivation. It is therefore extremely useful to follow-up this question by asking:

‘Why have you chosen that number? What does number x mean to you?’

You may also choose to ask young people about situations which might cause this number to increase and for them to consider changing their drinking to be more important. This approach is particularly useful with young people who report that they do not consider change to be very important.

This section also asks young people to consider how confident in their ability to change. Again, this should be posed as a scaling question:

‘On a scale of 0-10, where 0 is not confident at all and 10 is very confident, where would you place yourself with regards to how you are in your ability to change your drinking?’

It is again extremely useful to follow-up this question by asking:

‘Why have you chosen that number? What does number x mean to you?’

As the confidence scaling question is concerned with identifying barriers to change, it is helpful to encourage the young person to consider ways in which they can overcome these barriers and in doing so, increase their confidence:

‘How can I help you get from where you are now to a higher number?’ Or ‘what would have to happen for you to feel more confident in your ability to change your drinking?’

The responses provided in step 4 could be useful in step 6.

Step 5: ‘What do I think about reducing my drinking?’

In step 5, ask the young person what they think about reducing their drinking. As in step 4, it is important to think about both what they think are the bad things and also what they think are the good things about reducing their drinking. Make sure you start with the bad things about reducing before discussing the good things in order to encourage a positive view of reduction. If needed, use the information that the young person has already provided in step 3 and 4 as a prompt; a good thing about the young person reducing their drinking will always be reducing the risks and the bad things that they previously identified about their drinking.

‘What might be a bad thing about thing about reducing my drinking?’/ ‘What do you think are the good things about reducing your drinking?’

Step 6: 'What could I do about my drinking?'

In Step 5, young people should be encouraged to consider making an action plan and a coping plan to change their drinking. Discuss some of the things they could do to reduce their drinking. After identifying actions, prompt the young person to consider a coping plan. Ask if there are times when it might be difficult to achieve or maintain these changes before encouraging the young person to think of things or people which may be able to assist him/her to achieve or maintain change.

Ensure that the young person is coming up with plan for themselves. It is OK to prompt them but it will work best if the young person comes up with their own ideas. Some young people will not want to make a plan at all.

Summarise everything you have discussed from step 1 through to step 6. Take a copy of the sheet to give to the young person. Store a copy of the sheet securely in a locked cabinet. The research team will collect the sheet.

Issuing the alcohol information leaflet:

"These leaflets describe what we have just discussed in more detail. Take these away with you and please take the time to read them. There are contact details should you need further help/advice".

"Thank you for taking part in the project. These leaflets will provide you with some advice about alcohol and risks. Please take time to read the leaflet. We are also giving you some contact details if you would like any further help or advice."

Closing the session:

Finally, the young person should be informed that (i) their class will be asked to fill in a similar questionnaire in 6 and 12 months time; (ii) they will be asked to attend a session with a learning mentor in 12 months time to fill out an additional questionnaire, which should take and no longer than 20 minutes; and (iii) they may be invited to take part in an interview with a member of the research team exploring their views on the research project.

No further information needs to be discussed and the young person should be thanked again and the session completed. Remember to document the end time of the intervention on the A3 tool.

INTERVENTION 2 ONLY: Explain that you would like to arrange a family meeting and ask the young person if it is ok to contact their parent(s). THE YOUNG PERSON MUST INDICATE THAT THIS IS OK BY TICKING THE BOX ON THE CONSENT FORM.

Also check with the young person if it is ok to use the A3 intervention tool in any meeting with the parent(s). **IF THEY HAVE AGREED TO YOU CONTACTING THEIR PARENT(S)** explain that you will be talking to their parent(s) in the next couple of weeks to arrange this meeting and you will let them know when this is done.

No further information needs to be discussed and the young person should be thanked again and the session completed. Remember to document the end time of the intervention on the A3 tool.

INTERVENTION

2

INTERVENTION 2

Organising and facilitating the family meeting

If the young person agrees that they are happy for their parents/family to take part, parents should be contacted and invited to a meeting (which we expect will take up to one hour) via telephone or letter. The parents should be advised that any member of the family can attend the meeting.

This meeting should take place within one month of the 1:1 session, at a date and time which is convenient to all parties. It is anticipated that this could be after school hours and will be on school premises or another suitable venue. It is preferable that this meeting is not arranged within the family home. The research team can help arrange this meeting.

Written and informed consent from parents **must** be sought prior to delivering the intervention using the consent form provided to you by the research team (see below).

Without a completed consent form, the session cannot take place. This form should be signed and dated by both the participants and learning mentor; and a copy provided to the parents (or other family members). A separate consent form will be needed for each participant. The original copies need to be stored securely in a locked cabinet until the research team collects them.

SIPS JR-high



Parental Consent Form



*To be completed by a parent or guardian who **DOES NOT AGREE** to their child taking part in the SIPS JR-HIGH Young People and Alcohol study at their child's school.*

Please
Tick
Box

Name of Researchers: Stephanie O'Neil and Dr Dorothy Newbury-Birch

1. I confirm that I have read and understand the participant information leaflet dated 10/08/2011 (version 1) for the above study and have had the opportunity to ask questions.
2. I **DO NOT** wish my child to take part in the above study

☐
☐

Please use BLOCK CAPITALS

Your name

Child's full name

Child's school

Signature of parent / guardian

Date

It is important to begin building rapport with the family from your first contact to arrange a convenient date and time for the meeting. It is advised that the learning mentor who contacts the parents is the person who is expected to be present at the family meeting.

Wherever possible, contacting parents by telephone is preferable. If you cannot get in touch, try calling at different times of the day or contacting the other cases on your list first. If you still cannot get in touch after several attempts, then parents should be contacted by letter.

WHAT TO SAY WHEN CONTACTING THE PARENTS / FAMILY

“As you know, a research study about alcohol has been taking place in school, aimed at finding out whether it is possible to advise young people about alcohol. Your (young person’s name) has taken part, and spoken to me about alcohol. (Young person’s name) has agreed for us to contact you to see if you are happy to take part in the study. Taking part would involve coming along to a meeting, so that we can get your views and to give you all the opportunity to discuss alcohol as a family. I think this meeting will last up to an hour. Would you like to take part? When would be a convenient time for the meeting to take place?”

The start and end time of the session should be recorded in the box provided on the intervention tool. The aim of the session is to give young people an opportunity to consider their drinking, from the perspective of their parents/family members and also to fully involve the parents/family members in the development of a family action plan which seeks to support the young person to reduce their drinking. It is recognised that in order to involve the parents/family members in the action plan, the parents/family members motivation may also need to be explored and developed. Similarly, parental/familial behaviours and attitudes maybe negatively influencing the young persons drinking. If this is the case, it is likely to be appropriate for these issues to be discussed within familial change. Further advice will be given as to how to approach these issues.

The session will be structured around a 4-step tool (see below). This A3-sized, interactive document is designed to promote a conversation between yourself, the parents/family members and the young person about the young person’s alcohol use, parents/family members views of the young person’s drinking and a plan for change.

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BUILDING RAPPORT

It is important that you begin to build rapport with the family from the very beginning of your interaction. Indeed, this process starts from your first contact when arranging a convenient date and time for the meeting. When the parents/family members and the young person arrive for the family meeting, ensure that you welcome them all in a friendly and warm manner. An informal communication style is beneficial when introducing yourself and the meeting. It might be that you are able to make connections with the family at this early stage by discussing matters not related to the meeting (the weather, their journey into the school, how their day has been etc). This assists the family and the young person to feel at ease and therefore benefits the intervention.

INTRODUCE THE INTERVENTION

"Thank you for coming today. As you know, some people say that young people are drinking too much nowadays (pause), I don't know if you would agree with this? Our project is aimed at finding out how many young people do drink in a way which may be risky and whether it is possible to advise young people about alcohol. Your (young person's name) has been generous enough to talk to us about their drinking. Our meeting today aims to build upon that, to seek your views and to give you all the opportunity to discuss this as a family."

It is always advisable to avoid any implied criticism of either the young person or the family. Always, in a natural way, find something to praise the young person about for example:

"I found (insert the young person's name) to be an intelligent, thoughtful young person" or if disinhibited and loud, "a really energetic young man...very kind in the way he talked about his friends..."

After beginning to build rapport and introducing the intervention, you are now in a position to progress to delivering the intervention tool. During the level two intervention, it is advised that the learning mentor should write the young person's and parents/family members' responses on the level two intervention sheet.

Step 1: 'Young person's views on previous, 1:1 session'

The purpose of step 1 is to facilitate communication between the young person and their parents/family members about the young person's drinking. Fundamental to this step however is the fact that the young person leads the discussion and shares information that they feel comfortable to discuss in front of their parents/family members. Therefore, do not advise the parents/family members of what was discussed. Rather, learning mentors should invite the young person share their recollection of the discussion held during the level one intervention. Remember that rapport building is an on-going process throughout step two intervention and every effort should be made to ensure no party feels judged. It maybe

useful to open this step by asking the young person about their views of the level one intervention:

'You and I met approximately one month ago and we had a discussion, how do you think that discusses went? What do you remember from our chat?'

You can use prompts to facilitate the young person to share information with the parents/family members:

'When we met, we had an interesting conversation and talked about a number of things including your drinking. What do you remember about what we talked about?'

It may also be useful to consider if there has been any change in the young person's drinking or wider situation since the level one intervention:

'Thank you for sharing your memory of what we talked about. Has there been any changes since we last met?'

This information provides the context for the remaining discussion.

Step 2: 'What are your views about your child's drinking? Do you have any concerns'

Step 2 provides an opportunity to explore the aspects of the young person's drinking discussed in Step 1. The parents/family members may already be aware of the young person's drinking and therefore hold a view about whether this is acceptable or something to be concerned about. Alternatively, parents/family members may not have known that the young person drinks/frequency or amount of drinking. Step 2 encourages the parents/family members to consider their views. The purpose of this step is to encourage the young person to view their drinking from their parents'/family members' perspective, thus develop the young person's motivation to change. In addition however, parents/family members who facilitate the young person's drinking maybe encouraged to consider the risks associated with the young person's drinking and therefore develop motivation to change facilitative practice. Allow the parents/family members to identify their views and concerns themselves. If they do not express any concerns you may wish to prompt. Use the answers from step 1 to help you do this. Ask the young person what they think about their parents'/family members' views/concerns.

Summarise the main points; move on to Step 3.

Step 3: 'How important is it to me that my child changes their drinking?'

This step asks the parents/family members to consider the importance of the young person changing their drinking. The purpose of this section is to encourage the young person to

consider their parents'/family members' desire for the young person to change. It is expected that this exploration has the potential for positive development of the young person's motivation. As in step 2, parent's/family members are also encouraged to consider their own motivation for the young person to change their behaviour. This in turn may motivate parents/family members who facilitate their child's drinking to change their behaviour also. This is important precursor for step 4. Start by asking the parents/family members:

'On a scale of 0-10, where 0 is not important at all and 10 is very important, where would you place yourself with regards to how important it is to you for your child to change their drinking?'

A numerical response alone does not provide any insight into the parents'/family members' motivation. It is therefore extremely useful to follow-up this question by asking:

'Why have you chosen that number? What does number x mean to you?'

You may also choose to ask parents/family members about situations which might cause this number to increase and for them to consider their child changing their drinking to be more important. This approach is particularly useful with parents/family members who report that they do not consider change to be very important.

This section also asks parents/family members to consider how confident they are in their ability to support their child to change. Again, this should be posed as a scaling question:

'On a scale of 0-10, where 0 is not confident at all and 10 is very confident, where would you place yourself with regards to how confident you are in your ability to support your child to change their drinking?'

It is again extremely useful to follow-up this question by asking:

'Why have you chosen that number? What does number x mean to you?'

The confidence scaling question is concerned with identifying barriers to supporting change. Research tells us that young people exposed to familial alcohol misuse are more likely to start drinking at an earlier age and to drink heavier. It maybe therefore that parents/family members disclose their own difficulties with alcohol during this step (*"how can I encourage my child to reduce their drinking when I cannot reduce my own?"*) As with any identified barrier to supporting change, it is helpful to encourage the parents/family members to consider ways in which they can overcome these barriers and in doing so, increase their confidence:

‘How can I help you get from where you are now to a higher number, where you feel more confident in your ability to support your child to change their drinking?’ Or ‘what would have to happen for you to feel more confident in your ability to support your child to change your drinking?’

The responses provided in step 3 could be useful in step 4. For example, parents with alcohol problems may feel like they would be better able to support their child to change their drinking if they also achieve change.

Step 4: ‘Family action plan’

In Step 4, young people and parents/family members should be encouraged to consider making a family action plan and a coping plan to support the young person to change their drinking. Using the information gathered in both level one and level two interventions, encourage the family to consider the benefits for the family unit and/or the individuals within the family, of change. The parents/family members and the young person should identify the benefits for themselves; encourage agreement and ensure that all parties feel included.

‘What are the good things that might come from (insert young person’s name) changing their drinking? What are the good things for (insert the young person’s name)? What are the good things for the family as a whole?’

After the family has identified the benefits of change, it is important that the family reach achievable goals, which they all agree upon. Your role here is to facilitate discussion, rather than suggest goals. After identifying goals, prompt the family to consider a coping plan. Ask if there are times when it might be difficult to achieve or maintain these changes. Remember to encourage the young person and parents/family members to contribute. It is important that the family see this as a shared goal, which they work towards together.

Ask the young person and the parents/family members to consider times or situations which might make it difficult for the young person to achieve or maintain change. Encourage the young person and parents/family to contribute, both in terms of their perception of the young person’s barriers for change and the factors which may present a barrier to the parents/family members supporting the young person to change. Remember to use the information from step 1 and step 3 and prompt the family to consider relevant factors.

Examples of barriers to change for the young person include:

- All/most of the young person’s friends might drink alcohol
- The young person may feel that there is ‘nothing else to do’
- The young person may be worried about how their friends will perceive them if they stop/reduce drinking

Examples of barriers for the parents/family members supporting the young person to change their drinking include:

- A parent/family member may be experiencing alcohol problems themselves
- The young person and parent/family member (including sibling) may drink alcohol together
- The parents/family members may buy alcohol for the young person or have alcohol in the house, which the young person drinks
- The parents/family members may not be available to supervise the young person during the occasions that the young person drinks due to work/socialising
- The parents/family members may not have perceived a need to impose house rules and restrictions upon the young person prior to the meeting

It is always difficult to raise sensitive issues such as parental alcohol use. It maybe that the young person and parents/family members will share this information without being prompted. If barriers to change and supporting change are not identified, you may find that it is useful to draw the family's attention to some of the information on the intervention sheet. For example, there is an information box on the intervention sheet which advises that both parents and friends may influence a young person's drinking. You could try saying:

'Both parents and friends may influence a young person's drinking. This can be in both a positive and a negative way. Do you think there is anything in or outside of the home that may influence (insert young person's name) drinking?'

Whilst the focus of the intervention is to effect change in the young person's drinking, the parents/family may also need to change in order to support it. For instance, parents/family members may drink alcohol in a risky way and the family may agree that both the young person and the parent/family member will reduce their drinking. It may be appropriate to refer the parent/family member to a local service; contact numbers of alcohol services are provided in your pack. Young people's drinking maybe sanctioned and facilitated by parents/family members and the family may agree that in order to support the young person to reduce their drinking, the family will purchase less alcohol. Another way in which the family could work together to support the young person to change is to agree that the young person comes home at an earlier time on the evenings they drink alcohol or that the family may alternatively spend time together, without the use of alcohol. Fundamentally, the family can play a crucial role in supporting, encouraging and celebrating change. Ask the young person and parents/family members how they might prepare for and deal with the difficult times which they have identified, who can support change and how this can be achieved. It may be appropriate for the family to consider how they will recognise and celebrate change as a family also. This may involve a 'reward' activity such as ordering pizza or visiting the cinema once change has been achieved or maintained.

DEALING WITH DIFFICULT DISCLOSURES

If you are concerned about the welfare of the young person, it is imperative that you follow your usual safeguarding procedures. Every school will have their own policy and procedures which will provide advice on who to discuss and report safeguarding concerns to. National guidance is also available: www.education.gov.uk/publicationDetail/Page1/DCSF-00305-2010 (eg section 2.72)

CLOSING THE SESSION

Closing and ‘winding down’ appropriately can often be important. We suggest that you take some time after the intervention to debrief the family. This may include chatting about how they feel about the plan that they have agreed together. The provision of refreshments at this point maybe useful and can be offered whilst you photocopy the Intervention 2 sheet for the family to take away (the research team will collect the original sheet). A similar communication style to that encouraged within the ‘building rapport’ stage of the intervention is encouraged here, in order to promote comfort within the family before they leave.

Issuing the alcohol information leaflet:

“This leaflet describes what we have just discussed in more detail. Take it away with you and please take the time to read it. There are contact details should you need further help/advice.”

“Thank you for taking part in the project. This leaflet will provide you with some advice about alcohol and risks. Please take time to read the leaflet. We are also giving you some contact details if you would like any further help or advice.”

Thank all parties for their contribution to the meeting and their involvement in the study.

12 Month Follow Up

Preparation and Support

a. Prior to Follow Up Appointments

This training pack contains a list of young people from your school who met with you a year ago and took part in a session about alcohol as part of this research project. Each young person will now be asked to meet with you and complete a follow up appointment.

You have been given a separate pack for each young person who requires a follow up appointment. This pack contains all of the resources and information that you will need to deliver the follow up session.

Case-diary sheets for each young person have been returned to you and are included in the packs. Here, you should record any interactions to do with the relevant young person. Every time you attempt or do have contact with the young person should be recorded on this document – this is important as it will enable to look at how long is spent arranging and carrying out the follow up session.

b. During Follow Up Appointments

Just like in the previous stage of the research project, the researcher will organise regular meetings or telephone calls / emails to answer any questions or concerns; collect completed follow up sessions; and chase up outstanding follow up appointments. You can contact the research team at any time with any questions or concerns.

c. Date management and storage

All data relating to the study must be kept confidential. After every interaction with a young person it is important to make sure that documentation is kept in secure locked cabinets.

A member of the research team will visit the school at least once per week to collect any finalised documentation.

12 MONTH FOLLOW UP

Delivering the Follow Up Session

The start and end time of the follow up session should be recorded on each young person's case diary sheet, and in the box provided on the Timeline Follow Back Form completed by you and the young person.

The aim of the session is to:

- * Explore any changes in a young person's drinking 12 months after the original intervention, using three different screening questionnaires.
- * Establish the proportion of young people who successfully receive a follow up appointment 12 months after the original intervention.

Both aims are important to the development of a larger, national research study – we are keen to understand more about drinking in this age group, but at this stage we are also testing the tools to establish the best way to examine alcohol use in a school setting.

During the follow up session, each young person will be asked to fill out three separate questionnaires:

- * Single Alcohol Questionnaire (SAQ); * Alcohol Use Disorder Identification Tool (AUDIT)
- * Timeline Follow Back (TLFB) 28

The SAQ and AUDIT are to be completed by the young person on their own, in confidence, whereas the TLFB (like the intervention sheet that some young people completed 12 months ago) is much more interactive and to be completed by you and the young person together. ***It is important that the young person fills out each questionnaire in the order in which they are placed in the YP's envelope – the TLFB questionnaire should always be completed last.***

Introduce the Follow Up Session:

'Thank you for coming to see me today. You may remember coming to see me about a year ago and answering some questions about alcohol. At the end of our appointment, I mentioned that you would be asked to come back and see me to fill out another questionnaire. This is because Newcastle University are following up all young people who took part to see if anything has changed in the past year. Are you still happy to take part in the study? This is the last time you will be asked to come along to see me as part of this research project. Whatever we talk about will stay between you and me unless you tell me something that may place you or someone else at serious risk of harm.'

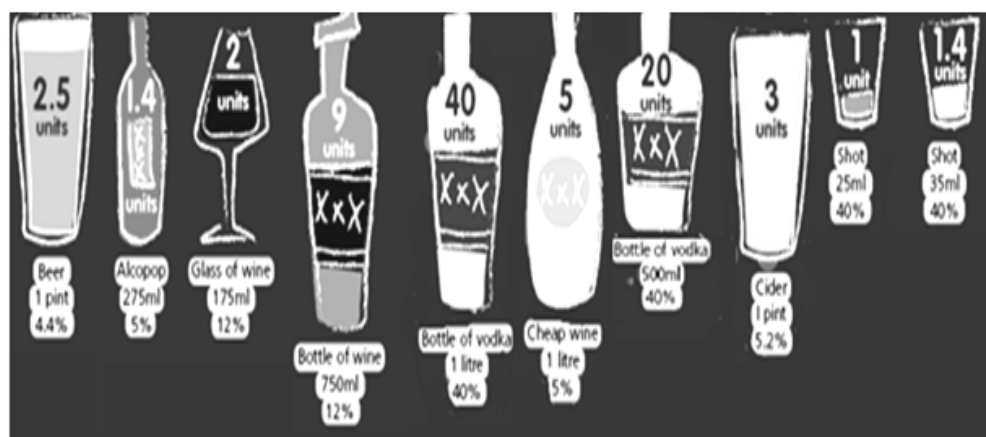
If the young person is still happy to take part, continue with the session. If a young person is unhappy to continue for any reason, thank them for coming to see you and stop the follow up session. Remember, a young person is free to change their mind at any point, and they do not have to give a reason for this. **If a young person does decide that they no longer want to take part it is important to inform the researchers as soon as possible.**

The remaining sections of this manual will explain how to complete all three screening questionnaires.

a. The SAQ:

SAQ - TO BE COMPLETED BY THE YOUNG PERSON ON THEIR OWN

The following questions ask about the alcohol you have drunk in the last 12 months. The questions ask about how many standard drinks (units) you have consumed. A description of a standard drink is given in the box below. So, for example, a pint of regular beer or lager is equal to 2.5 standard drinks.



In the last 12 months how often have you drunk more than 3 units of alcohol?

Never	Less than 4 times	4 or more times but not every month	At least once a month but not every week	Every week but not every day	Every day
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Completing the SAQ: Young people must complete the SAQ on their own, confidentially.

Young people have completed this questionnaire three times before and should recognise it. It is one of a number of questions in the larger survey completed by the whole year group at baseline and anonymously at 6 and 12 months. We are asking young people recruited into the main study to complete it again so that we can compare their answers with those they gave 12 months ago when they completed the first questionnaire and left their name.

b. The AUDIT:

AUDIT - TO BE COMPLETED BY THE YOUNG PERSON ON THEIR OWN		AUDIT - TO BE COMPLETED BY THE YOUNG PERSON ON THEIR OWN	
<p>The following questions ask about the alcohol you have drunk in the last 12 months. The questions ask about how many standard drinks (units) you have consumed. A description of a standard drink is given in the box below. So, for example, a pint of regular beer or lager is equal to 2.5 standard drinks.</p>			
<p>How often do you have a drink containing alcohol?</p>			
Never	Monthly or less	2 to 4 times a month	2 to 3 times a week
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>How many standard drinks containing alcohol do you drink on a typical day when you are drinking?</p>			
1 to 2	3 to 4	5 to 6	7 to 9
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>How often have you had 6 or more standard drinks if female, or 8 or more if male, on a single occasion in the last 12 months?</p>			
Never	Less than monthly	Monthly	Weekly
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>How often during the last 12 months have you found that you were not able to stop drinking once you had started?</p>			
Never	Less than monthly	Monthly	Weekly
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>How often in the last 12 months have you failed to do what was normally expected of you because of your drinking?</p>			
Never	Less than monthly	Monthly	Weekly
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>How often in the last 12 months have you needed an alcoholic drink in the morning to get you going?</p>			
Never	Less than monthly	Monthly	Weekly
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>How often in the last 12 months have you had a feeling of guilt or regret after drinking?</p>			
Never	Less than monthly	Monthly	Weekly
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>How often in the last 12 months have you not been able to remember what happened when drinking the night before?</p>			
Never	Less than monthly	Monthly	Weekly
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Have you or someone else been injured as a result of your drinking?</p>			
No	Yes, but not in the last year	Yes, during the last year	Yes, during the last year
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Has a relative/friend/doctor/health worker been concerned about your drinking or advised you to cut down?</p>			
No	Yes, but not in the last year	Yes, during the last year	Yes, during the last year
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Completing the AUDIT: Young people must complete the AUDIT on their own, confidentially. Like the SAQ, young people have completed this questionnaire three times before and should recognise it. It is one of a number of questions in the larger survey completed by the whole year group at baseline and anonymously at 6 and 12 months. We are asking young people recruited into the main study to complete it again so that we can compare their answers with those they gave 12 months ago when they completed the first questionnaire and left their name.

c. The TLFB:

Name of Young Person: _____

Name of learning mentor: _____ School: _____

Date: _____ Start Time: _____ End Time: _____

Case ID (Office Use Only): _____

SIPS JR-high

TIMELINE FOLLOWBACK CALENDAR: 2013



To help us evaluate your drinking, we want to get an idea of the amount of alcohol you have drank in the past 28 days. To do this, we would like you to fill out the attached calendar with the learning mentor.

- ✓ Filling out the calendar is not hard
- ✓ Try to be as accurate as possible - it is important that you answer each question as thoughtfully and frankly as possible.
- ✓ This is not a test and there are no right or wrong answers - *We recognize that you won't be able to remember everything perfectly and that's okay.*

COMPLETING THE CALENDAR:

- ✓ On days when you did drink, please write in the total number of drinks you had, including what type and brand of alcohol it is (e.g. '5 cans of Fosters')
- ✓ Please try to include the size and type of container (e.g. 300ml can)
- ✓ If you shared a drink with other people, please try to remember how much **you** drank – did you have the same amount as everyone else?
- ✓ On days when you did not drink, you should mark these with an 'A'
- ✓ ***It's important that something is written for every day, even if it is an 'A'***
- ✓ A blank calendar is attached. Write in the number of Standard Drinks that you had each day.
- ✓ **Double check that ALL days are filled in before returning the calendar.**
- ✓ Thank you for taking part!

Mon	Tue	Wed	Thu	Fri	Sat	Sun
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30 Nov	1	2
3	4	5	6	7	8	9 Dec

Yesterday

The TLFB measures alcohol consumption over a given period of time. In this study we are measuring the past 28 days. The questionnaire is based on asking participants to estimate / recall their daily alcohol consumption and can examine total alcohol consumption *as well as* patterns of alcohol consumption. The TLFB form looks a little bit like a 'drink diary'.

Preparing the TLFB form:

There is a different copy of the TLFB form to be used for each date during the follow up period. Dated copies of the form have been organised for you into a folder (and provided to you with your training pack). *For example, if you decide to hold an appointment with a young person on 2nd February, please make sure you use a form dated 2nd February from your file.*

Dated copies of the form are also marked with memorable dates (such as Christmas, exam periods, football games). Memorable dates which are specific to the young person (such as their birthday or family occasions) will need to be filled in when the young person is in the room with you – don't spend too long on this, the first 2-3 minutes of the session should be enough. Memorable dates can work as really good prompts to ease the young person into filling out the TLFB.

Filling out the TLFB form:

The aim is to fill in the amount of alcohol consumed for each day (represented by a box in the grid). The TLFB questionnaire is interactive and designed to be filled out by you and the young person together. When completing the form, the key information that you want to find out is:

- * When the young person drank alcohol
- * The type (and brand) of alcohol that they drank
- * Volume of alcohol consumed

There are different ways of identifying how much alcohol the young person has consumed. First, think about the size and type of container (e.g. bottle or can / 300 or 500ml). Remember that a young person may not always drink all of this to themselves – in this case, make a note of the proportion of the container that they think they drank, the number of people that they shared this with and whether everyone drank the same amount – any / all of this information is helpful. Finally, days when a young person did not drink should be marked with an '**A**', which stands for 'abstinence' (no drinking at all on that day).

In terms of volume, very few young people know the size of bottles or other containers. Being able to show the size of a bottle with your hands and having some background

knowledge yourself can help in working with the participant. Sometimes asking how much it cost and where it was purchased can help with your detective work.

Eventually, the completed form should look something like this:

Mon	Tue	Wed	Thu	Fri	Sat	Sun
12	13	14	15 1 x 175 ml White Wine	16 1 x 175 ml White Wine	17	18
19	20	21	22	23	24	25
26	27	28	29	30 Nov PAYDAY	1st xmas tree up! 2 x 175 ml red wine	2 SAFE V NORWICH 2 x 330 ml Pilsner, 1 x 175 ml V
3	4 GRADUATION 1 Moët 1st Foster's 1 x 175 ml White Wine	5	6 1 x 175 ml White Wine	7 1 x 175 ml White Wine	8	9 Dec A's BIRTHDAY ROCKCLIFFE HALL 4 x 175 ml glass of Wine

Yesterday

Notes:

* Always has xmas afternoon tea with mam; Shared two bottles of wine - may not be accurate - 'top ups' - 1 good wine, what does this mean ???

2 Dec - xmas shopping with Dad - had lunch with drinks

food & drinks - it's not a regular thing?

4 Dec - Red graduation; Celebration, food again.

Drinks several times in the month in house with father - pattern ???

Getting started:

Some people find the TLFB quite challenging as there are no set questions to ask. It is more a process of questioning to establish what (and how much) young people drink, and the background to their drinking which enables you (as the researcher) to build up a pattern of drinking and complete the chart. Essentially, you want to build up a picture of each young person's drinking over the last 28 days. The following tips are useful ways to get started:

- Find out when they last had a drink of alcohol?
- What was the background to this?
- What was the situation?
- Where was it consumed?
- When was this?
- How often does this happen?
- Is this usual?
- Do they ever drink more/less than this?
- Are there any other times that they've had a drink of alcohol?

A 'notes' page has been provided for you – please use this to scribble down any information that you think might be useful as you go through the form. Write down everything because, as the story unfolds, the information can help you piece together a picture of their drinking behaviour. This notes page is really important to us – remember that we are also trying to explore the implications of examining alcohol use in a school setting in this way.

Be alert to patterns of drinking behaviour – this will make completing the form much easier because it enables chunks / consecutive weeks of the TLFB to be completed. Some young people may be reluctant to disclose their alcohol use. Don't be afraid to prompt or ask specific questions to help these young people to discuss their drinking – ask as many as you think fits the participant.

Listen carefully and draw on everything they say. If they mention something in passing or in answer to another question, pick up on it as a prompt. When it comes to establishing frequency often giving a timeframe can help. For instance, if someone says they drink with mates you might ask if this happens 2-3 times a week or once every week depending on the participant. Sometimes picking an extreme (e.g. every day) can help you work towards something in correct range.

Some examples of what you could say:

"I'd like to ask you about your drinking during this period. The things already recorded on the calendar here may help you remember better. First of all, were there any periods or days when you had nothing to drink at all?"

"Could you describe for me a usual or typical week of drinking?"

"Now that we have your regular pattern, I'd like you to tell me about any times during this period when your drinking was different from this. Look at the calendar again, and think back over this period. When were times that you had more or less than your regular amount to drink?"

"If you didn't have a regular pattern from week to week, tell me about the times when you did drink during this period on this calendar."

"Some young people tell me that they drink in weekends. Is this something that you do?"

Other points you could explore are whether the young person:

- buys alcohol
- asks someone to buy alcohol for them
- gets alcohol from friends or family
- drinks at parties, with friends, with family, alone?
- drinks at home, in the park, at a friends house, elsewhere?
- ever gets really drunk, get tipsy?

Above all, listen to the young person and use your intuition – building a rapport and interviewing skills (which you all have in abundance) are key to the young person

completing the form as accurately as possible. Remember to reassure the young person that this is not a test and there are no right or wrong answers – *young people won't be able to remember everything perfectly and that's okay*. If a young person struggles, ask them for an estimate or their 'best guess' – this is better than no information at all.

Closing the follow up session:

No further information needs to be discussed and the young person should be thanked again and the session completed. Remember to document the end time of the session, and place all completed documents in the envelope which relates to the young person securely and confidentially. Envelopes will be collected by the researcher.

Appendix 4 Qualitative study

Information sheet for interviews

Who is funding and organising the study?

The study is funded by the National Institute for Health Research (NIHR) and sponsored by Newcastle University.

What happens to the results of the study?

We're happy to send you a report at the end of the project if you're interested. The study will be printed in academic journals and presented at conferences. You will not be identified in any of the information written about the study.

Will the research help me?

We can't promise that this study will help you directly. However, the study may give you the chance to talk openly about alcohol. The information that you give will be used to help understand the decisions you and other young people make.

For further information and advice about your drinking...

- Talk to Frank: [REDACTED]
- Speak to Drinkline: [REDACTED]
- For local support, contact Never 2 Late (N2L), North Tyneside on [REDACTED]

Thank You...

for taking the time to read this leaflet. Please ask your teacher or Learning Mentor to answer any questions or concerns you may have about the project. If you decide to take part, please keep this leaflet for future reference.

Any suggestions and complaints about the study or how you were treated will be dealt with, in writing, within 7 working days. They should be made in writing to Dr Dorothy Newbury-Birch at the address below.




Dr. Dorothy Newbury Birch
Alcohol Research
Programme Manager

Stephanie O'Neil
Research Associate

Institute of Health & Society, Newcastle University
Baddiley-Clark Building, Richardson Road,
Newcastle upon Tyne, NE2 4AX

Telephone: [REDACTED]

SIPS JR-high

SIPS JR-high

Research Information Leaflet Version 1 18.10.11

SIPS JR.HIGH

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What is this study about?

You are being invited to take part in a research study about alcohol. This leaflet is for you to keep. Please read it carefully and take time to decide if you want to take part or not. Talk to other people about the study if you want to. Please ask us if there is anything that you don't understand or that you would like more information on.

What will happen to me if I take part?*The Questionnaire*

We want to understand more about alcohol use among people your age. During school time your class will be asked to fill out a questionnaire. **The questionnaire will explore smoking, sexual health and general attitudes to health as well as alcohol use.**

You can choose not to complete the questionnaire; to complete it anonymously or with full contact details. There are no right or wrong answers. Your answers will not be passed on to parents or teachers.

You will be asked to place your completed questionnaire in a blank envelope and seal it yourself. Sealed questionnaires will be collected by the research team.

You will receive a compensatory £5.00 gift voucher after completing the questionnaire.

We will return to your school and ask your class to complete an additional questionnaire about alcohol in 6 and 12 months time.

The Study

We also want to find out whether young people would benefit from receiving advice during school time about their drinking behavior.

After completing a questionnaire you may be invited to receive advice about changing your drinking behavior, delivered by staff at your school.

Completing a questionnaire does not mean that you have to take part in the rest of the study.

Advice may consist of a leaflet; a 30 minute personalized session; or an extended one hour session (to which parents will be asked to attend). The type of advice you receive will be chosen at random by the research team.

Do I have to take part?

It's up to you to decide.

We will describe the study, go through this information sheet with you and answer your questions. If you decide to take part in the study, you'll be asked to sign a consent form.

You're free to change your mind at any time; you will not need to give a reason. If you do decide not to take part in the study, any information you give will be destroyed.

Who will have access to my information?

All information collected about you during this research will be kept confidential. The only people who will be able to look at it will be the research team at the University.

All information will be stored on a password protected computer. Data will be kept for 10 years within the University according to the rules of the Data Protection Act. After 10 years, the data will be destroyed securely.

Data from school records may be looked at by members of the research team only if it is relevant to this research.

Researchers work to the same rules of confidentiality as doctors and nurses which can only be broken, without your consent, in very exceptional circumstances. **Usually this is if the researcher sees or is told something which raises serious concern for your personal safety.**

Could I be at risk by taking part?

We're confident that you will not experience any harm as a result of taking part in this research study. However, if it is proven that you are harmed during the research, and this is because of the researcher's lack of care, you may have grounds for legal action against Newcastle University. You may have to pay your own legal costs.

SIPS JR-high



Participant Consent Form (Interviews)



Please read each of the following statements and tick the box if you agree with the statement. If you have ticked all of the boxes please sign and date the form.

**Please
Tick
Box**

1. I confirm that I have read the participant information leaflet dated 21/10/2011 (version 1) for the above study. ☐
2. I confirm that I have had the opportunity to ask any questions about the study and any questions I have asked have been answered to my satisfaction. ☐
3. I understand that taking part is voluntary and that I'm free to change my mind at any time without giving any reason and without my legal rights being affected. ☐
4. I understand that any data created from this study will be held in a locked filing cabinet for ten years after which the data will be destroyed. All data collected will be anonymous and kept confidential, and only members of the research team will have access to this data. ☐
5. ***I agree to take part in the above study. I am aware that a copy of this consent form will be provided to me for my records.*** ☐

Name of Participant

Date

Signature

Name of Witness

Date

Signature

Participant Consent Form (Interviews) Version 1 21/10/2011

TABLE 22 Interview schedules

School lead liaisons		
Big research question	Mini research question	Ways to approach this question
How do they view alcohol use by young people and existing alcohol education within their school?	What are the participant's thoughts or concerns about alcohol use by young people?	<p>What are your views about alcohol use by young people in general?</p> <p>What is your experience and what are your views about alcohol use by young people in your school?</p> <p>How does alcohol have an impact on the school environment? (<i>Probes</i>: direct impact, i.e. intoxication on school premises, and indirect impact, i.e. health impact on young people affecting educational attainment)</p>
	What are the participants' thoughts on existing alcohol education within their school?	<p>Is alcohol use by young people addressed in your school? How? By whom? (<i>Probe</i> on external initiatives)</p> <ul style="list-style-type: none"> • If yes, do you feel this is effective? Why? • If no, why is this? Do you think it should be?
How did the study impact on the school?	Why did they decide to participate in the study?	<p>Can you remember how the research project was initially discussed with you?</p> <p>Was the approach by researchers suitable?</p> <p>Whose decision was it to participate in the study?</p> <p>Why was the decision made? (<i>Probes</i>: what influenced the decision, concerns about alcohol use, did they find any aspect of the study particularly attractive, did they have any prior experience of research in the school, etc.)</p>
	What did they think of how the study was performed within their school?	<p>Can you describe the process of randomisation? Did you have concerns about the treatment condition to which your school was randomised?</p> <p>How did you find recruiting learning mentors to help with the study?</p> <p>Do you have any thoughts on the fact that the study focused on only Year 10 pupils? (<i>Probes</i>: whether this was the most suitable age group in terms of school practicalities and in terms of alcohol use by young people at this age)</p> <p>A survey was conducted in your school in December as part of the study: how did you find the completion of this survey in your school? Did you have any thoughts on providing the young people with gift vouchers? Did you have any thoughts on providing an opt-out letter to parents for involvement in the survey? (<i>Probes</i>: appropriate? Best way to go about it?)</p>

TABLE 22 Interview schedules (*continued*)

School lead liaisons		
Big research question	Mini research question	Ways to approach this question
		<i>For intervention 1 and intervention 2 schools:</i>
		What do you understand about what learning mentors are doing with young people who are found to be drinking in a way that might be harmful to them? What do you think about this?
		How did you find the process of enabling these interventions within the school environment? (<i>Probes:</i> learning mentor time, getting agreement from teachers for pupils to be taken out of class, etc.)
	Did the study have an effect on the staff and students involved?	Did any staff come to talk to you about the study? If so, who (learning mentors, teachers, governors) and why?
		Did any students talk to you about the study? If so, why?
		Did any parents talk to you about the study? If so, why?
		Do they think the study has had any wider effects on the school? (<i>Probes:</i> raising awareness of alcohol in school, positive effects, negative effects)
		How did young people find being taken out of class for the interventions? (<i>Probe:</i> any negative effects)
What lessons could be learned for future research?	Could anything have been done differently to make the research easier to perform in the school?	If you were approached again to take part in the research would you agree? Why?
		What worked well? Why?
		What didn't work well? Could anything have been done to overcome this?
		Do they think that alternative ways of performing the study would be helpful? (e.g. a video clip of a researcher informing students how to fill out the survey)
	How could study findings be effectively disseminated?	Are they interested in dissemination of study findings?
		To whom? Governors? Staff? Students? Parents?
		How do they think dissemination would be most effectively performed?

continued

TABLE 22 Interview schedules (*continued*)

Learning mentors		
Big research question	Mini research question	Ways to approach this question
What are the feelings regarding alcohol use by young people and existing alcohol education within their school?	Does the participant have any thoughts or concerns about alcohol use by young people?	<p>What are your views about alcohol use by young people in general?</p> <p>What are your views about alcohol use by young people in your school?</p> <p>What impact, if any, do you think alcohol use has within the school environment? (<i>Probes</i>: intoxication on school premises and indirect, e.g. health/educational attainment)</p>
	Does the participant have any thoughts on existing alcohol education within their school?	<p>Is alcohol use by young people addressed in your school? How? By whom? (<i>Probe</i>: external initiatives)</p> <ul style="list-style-type: none"> • If yes, do you feel this is effective? Why? • If no, why is this? Do you think it should be?
What were their experiences of being part of this project?	How did you feel about participation in the research project?	<p>How did you become involved in the research? (<i>Probe</i>: were they involved in the decision)</p> <p>How did you feel about being involved in the research? (<i>Probes</i>: concerns about alcohol use among young people, the form of intervention, concerns over their workload, the nature of their involvement, etc.)</p> <p>Do you have any thoughts on the fact that the study focused on only Year 10 pupils? (<i>Probes</i>: whether this was the most suitable age group in terms of school practicalities and in terms of alcohol use by young people at this age)</p>
	How did you find the training?	<p><i>Control group and intervention 1:</i></p> <p>What do you remember about the training you undertook?</p> <p>Did you have any thoughts on the training session about alcohol use? (<i>Probes</i>: usefulness, manner of delivery, etc.)</p> <p>Did you have any thoughts on the training session about the control and level one interventions? (<i>Probes</i>: usefulness, manner of delivery, etc.)</p> <p>Do you think the training adequately prepared you for taking part in the study?</p> <ul style="list-style-type: none"> • If yes, why? (<i>Probes</i>: any particular aspects, i.e. content of training or manner of delivery) • If no, why? (<i>Probes</i>: any particular aspects, i.e. content of training or manner of delivery)

TABLE 22 Interview schedules (continued)

Learning mentors		
Big research question	Mini research question	Ways to approach this question
		<p><i>Intervention 2:</i></p> <p>What do you remember about the training you undertook?</p> <p>Did you have any thoughts on the training session about alcohol use? (<i>Probes</i> on usefulness, manner of delivery, etc.)</p> <p>Did you have any thoughts on the training session about the control and intervention 1? (<i>Probes</i> on usefulness, manner of delivery, etc.)</p> <p>Did you have any thoughts on the training session about intervention 2? (<i>Probes</i> on usefulness, manner of delivery, etc.)</p> <p>Do you think the training adequately prepared you for taking part in the study?</p> <ul style="list-style-type: none"> • If yes, why? (<i>Probe</i> on any particular aspects, i.e. content of training or manner of delivery) • If no, why? (<i>Probe</i> on any particular aspects, i.e. content of training or manner of delivery)
	What were their experiences of delivering the intervention?	<p><i>Control group:</i></p> <p>Did you have any thoughts on the consent procedures? (<i>Probes</i>: opt-out letter for the survey, did they think young people really understood why they left their names on the survey)</p> <p>How did you find delivering the leaflet? (<i>Probe</i>: Was it difficult to identify a child as having screened positive and then not to do anything about it?)</p> <p>Is it possible for you to describe for me how you would go about this conversation with the young person? (<i>Probe</i>: Did they find themselves giving advice anyway?)</p> <p><i>Intervention 1:</i></p> <p>Did you have any thoughts on the consent procedures? (<i>Probes</i>: opt-out letter for the survey, did they think young people really understood why they left their names on the survey)</p> <p>How did you find delivering the one-to-one intervention within the school environment? (<i>Probes</i> on time and resource issues)</p> <p>Did you have any thoughts on the tool you were given to provide the intervention with?</p>

continued

TABLE 22 Interview schedules (*continued*)

Learning mentors		
Big research question	Mini research question	Ways to approach this question
		Is it possible for you to describe for me how you would go about delivering an intervention with a young person?
		Did you find the way that you delivered the intervention differed with different young people? (<i>Probe</i> : personality issues, etc.)
		Did you find the way that you delivered the intervention differed over time?
		Was there anything you found particularly enjoyable or easy about delivering the intervention?
		Was there anything you found particularly difficult about delivering the intervention?
		Would you change anything about the intervention?
		Did you think that taking the young person out of class had any negative impact on them?
		<i>Intervention 2:</i>
		Did you have any thoughts on the consent procedures? (<i>Probes</i> : opt-out letter for the survey, did they think young people really understood why they left their names on the survey)
		How did you find delivering the one-to-one intervention within the school environment? (<i>Probe</i> : time and resource issues)
		<i>Questions regarding intervention 1:</i>
		Did you have any thoughts on the tool that you were given to provide the intervention?
		Is it possible for you to describe for me how you would go about delivering an intervention with a young person?
		Did you find the way that you delivered the intervention differed with different young people?
		Did you find the way that you delivered the intervention differed over time?
		Was there anything you found particularly enjoyable or easy about delivering the intervention?
		Was there anything you found particularly difficult about delivering the intervention?
		Would you change anything about the intervention?

TABLE 22 Interview schedules (*continued*)

Learning mentors		
Big research question	Mini research question	Ways to approach this question
		<p>Did you think that taking the young person out of class had any negative impact on them?</p> <p><i>Questions regarding intervention 2:</i></p> <p>At what point did you discuss the idea of parental involvement with the young person?</p> <p>Did you have any thoughts on the tool that you were given to provide the intervention?</p> <p>How did you find discussing parental involvement with young people?</p> <p>How did young people tend to respond to the idea of parental involvement? Did they talk to you about their reasoning for wanting or not wanting their parents involved?</p> <p>How did you go about the initial approach to parents?</p> <p>How did you find discussing the family intervention with the parent?</p> <p>Was there anything that you found that made this conversation easier/harder for you?</p> <p>Is it possible for you to describe for me how you would go about delivering an intervention with a young person and their parents?</p> <p>Did you find the way that you delivered the intervention differed with different young people and parents? If so, how?</p> <p>Did you find the way that you delivered the intervention differed over time? If so, how?</p> <p>Was there anything you found particularly enjoyable or easy about delivering the intervention? If so, what?</p> <p>Was there anything you found particularly difficult about delivering the intervention? If so, what?</p> <p>Would you change anything about the intervention?</p> <p>How did you find trying to engage young people and their parents in conversation about alcohol use in this way? How appropriate did you find a one-off intervention for this type of work?</p>
		continued

TABLE 22 Interview schedules (*continued*)

Learning mentors		
Big research question	Mini research question	Ways to approach this question
What lessons could be learned for future research?	Could anything have been done differently to make the research easier to perform in the school?	<p>If you were approached again to take part in the research would you agree? Why?</p> <p>What worked well? Why?</p> <p>What didn't work well? Could anything have been done to overcome this?</p> <p>Do they think that alternative ways of performing the intervention would be helpful?</p>
	How could study findings be effectively disseminated?	<p>Are they interested in dissemination of study findings?</p> <p>To whom? Staff? Students? Parents?</p> <p>How do they think dissemination would be most effectively performed?</p>

TABLE 22 Interview schedules (*continued*)

Young people		
Big research question	Mini research question	Ways to approach this question
What role does alcohol play in the participants' lives?	What does the participant consider to be 'normal' alcohol use behaviour for them?	Can you remember when you first started to drink? (<i>Probe</i> : why first started)
		How often would you say that you drink alcohol?
		Could you describe to me a typical drinking occasion for you?
		What do you think are the positive things about drinking for you?
	What are the major influences on their alcohol behaviour?	Does drinking have any downsides for you?
		Do you think that you drink about the same as your friends? As the other kids in school? Why is this?
		Since you started drinking, have there been any times that you have drunk more than is usual for you? Why?
		Since you started drinking, have there been any times that you have drunk less than is usual for you? Why?
What were their experiences of being part of this project?	What did they think of the screening process?	Who would you usually drink with?
		What do you remember about how the study was first mentioned to you? Who talked about it?
		Can you tell me why you decided to write your name down on the survey?
		Did you feel that you understood what you were being asked to do and why?
	What was the personal impact of finding out that they had screened positive?	Can you tell me what the survey questions asked? How clear were they? Anything confusing? (<i>use questionnaire as aide-memoire</i>)
		How did you feel answering the questions on the survey?
		<ul style="list-style-type: none"> If uncomfortable, why? (<i>Probe</i> whether the material was too sensitive, were they worried that other people would read their answers)
		What was it like to fill in these forms in a classroom? Was that appropriate?
		Can you remember being told you had been found to be drinking in a way that might be harmful to you? What did you think this really meant?

continued

TABLE 22 Interview schedules (*continued*)

Young people		
Big research question	Mini research question	Ways to approach this question
		Can you tell me a little about what that experience was like for you? (<i>Probes</i> : Was it a surprise? Did it upset you?)
		How did you find having this conversation with the learning mentor?
	What influenced them to consent to take part in the study?	How was the study explained to you?
		Did you feel that you properly understood what taking part in the study would mean from this conversation?
		What made you decide that you wanted to take part (<i>Probe</i> : felt they had to, concerns over alcohol use)
		How did you feel deciding to take part in the study? If you had any questions, how did the learning mentor answer them?
	What were their experiences of receiving the intervention?	<i>Control group</i> :
		Can you remember what the learning mentor said to you after they told you that you had screened positive?
		Did you feel that that was enough information to help you?
		Did you have any thoughts on the leaflets you were given? (<i>Probes</i> : Did they read them? Useful?)
		<i>Intervention 1</i> :
		Is it possible for you to go through with me what happened during the meeting with the learning mentor?
		Was there anything you found particularly positive about the intervention?
		Was there anything you found particularly negative about the intervention? (<i>Probe</i> : being taken out of class)
		Did you have any thoughts on the leaflets you were given? (<i>Probes</i> : Did they read them? Useful?)
		<i>Intervention 2 – did not agree to parent contact</i> :
		Can you remember at what point the learning mentor asked you about contacting your parents?
		What do you think about involving your parent/s in a meeting? (<i>Probe</i> : Do you think it was appropriate to try and involve parents in this kind of intervention or is this something that should be handled by young people alone)

TABLE 22 Interview schedules (continued)

Young people		
Big research question	Mini research question	Ways to approach this question
		<p>Could you tell me a little more about why you didn't want your parents to be contacted? (<i>Probes</i>: feelings of embarrassment, thinking parents couldn't help, etc.)</p> <p><i>Intervention 2 – did agree to parent contact:</i></p> <p>Can you remember at what point the learning mentor asked you about contacting your parents?</p> <p>Could you tell me a little more about why you were happy for your parents to be contacted?</p> <p>How did your parents react to being contacted about the study?</p> <p>Is it possible for you to go through with me what happened during the intervention with your parents?</p> <p>Was there anything you found particularly difficult about the intervention?</p> <p>Was there anything you found particularly positive about the intervention?</p> <p>Do you think it was useful to you to have your parents involved in the intervention?</p> <p>Do you feel different about drinking now, compared with before you received the intervention?</p> <ul style="list-style-type: none"> • If yes, in what way? <p>Has your drinking changed at all compared with before you received the intervention?</p> <p>Has there been anything that you have found that helps you change the way you drink?</p> <p>Has there been anything that has made it particularly difficult to change the way you drink?</p>
	Has the intervention had any impact on perceived drinking behaviours?	
What do they perceive to be the appropriateness of school-led health promotion work across the school-home interface	Where does the participant perceive to be the most appropriate place to have alcohol education?	<p>What do you think of school as a place to have this kind of alcohol education?</p> <ul style="list-style-type: none"> • If positive response, why? • If negative response, why? Where would be more suitable?

continued

TABLE 22 Interview schedules (*continued*)

Young people		
Big research question	Mini research question	Ways to approach this question
What lessons could be learned for future research?	Could anything have been done differently to make the research easier to be part of?	<p>If you were approached again to take part in the research would you agree? Why?</p> <p>What worked well? Why?</p> <p>What didn't work well? Could anything have been done to overcome this?</p> <p>Do they think that alternative ways of performing the intervention would be helpful?</p>
	How could study findings be effectively disseminated?	<p>Are they interested in dissemination of study findings?</p> <p>To whom? Staff? Students? Parents?</p> <p>How do they think dissemination would be most effectively performed?</p>

TABLE 22 Interview schedules (continued)

Parents		
Big research question	Mini research question	Ways to approach this question
Sampling Information	SES status of school area and gender	What school does the participant's child attend?
What role does alcohol play in the participant's lives?	What does the participant consider to be 'normal' alcohol use behaviour for them?	How often would you say that you drink alcohol?
		Could you describe to me a normal drinking occasion for you?
		What do you like to drink?
		Have there been any times that you have drunk more than is normal for you? Why?
What were their experiences of being part of this project?	In what ways have the participants considered their child's alcohol use?	Have there been any times that you have drunk less than is normal for you? Why?
		What do you think are the positive things about drinking for you?
		Does drinking have any downsides for you?
		Have you ever had concerns about your child drinking alcohol?
		Is alcohol something that you have ever discussed with your child?
		<ul style="list-style-type: none"> • If no, why? • If yes, why and how?
		Can you remember receiving the original letter about the study with the opt-out slip?
		<ul style="list-style-type: none"> • If yes, did you understand what the letter was asking you to do? • Did you think the opt-out letter was appropriate/necessary?
		Can you remember how you found out that your child had been found to be drinking in a way that was possibly harmful to them within the study?
		Can you tell me a little about what that experience was like for you? (<i>Probes:</i> Was it a surprise? Did it upset you?)
		What did you think that 'drinking in a way that was possibly harmful' really meant?
		Can you remember the initial conversation you had with the learning mentor about taking part in the intervention with your child?
		Could you go through what was said at this conversation with me?
		Can you tell me a little about what this conversation was like for you?

continued

TABLE 22 Interview schedules (continued)

Parents		
Big research question	Mini research question	Ways to approach this question
	What were their experiences of receiving the intervention?	Is it possible for you to go through with me what happened during the intervention?
		Was there anything you found particularly difficult about the intervention?
		Was there anything you found particularly good about the intervention?
		Did you have any thoughts on the booklet you were given? (<i>Probes</i> : Did they read it? Was it useful?)
What do they perceive to be the appropriateness of school-led health promotion work across the school-home interface		What changes would you make to the way the meeting was arranged/conducted?
	Has the intervention had any impact on how they feel about and respond to their child's drinking behaviour?	Has the intervention made you feel differently about your child's drinking now?
		Do you think that having the intervention has had an impact on the way you discuss drinking with your child?
	Where does the participant perceive to be the most appropriate place to have alcohol education?	What do you think of school as a place to have this kind of alcohol education? Why?
		If not ideal, where would be more suitable?
	Does the participant think that parental involvement in this kind of alcohol intervention is appropriate?	How did you feel about being informed that your child had been found to be drinking in a way that might be harmful to them? Was this appropriate?
		How did you feel about being asked to be involved in the meeting with your child? Was this appropriate?
		Not all children, found to be drinking in a potentially harmful way and having met with a learning mentor to discuss this, have had an intervention with parental involvement. Do you have any thoughts on this?
What lessons could be learned for future research?	Could anything have been done differently to make the research easier to be part of?	If you were approached again to take part in the research would you agree? Why?
		What worked well? Why?
		What didn't work well? Could anything have been done to overcome this?
		Do they think that alternative ways of performing the intervention would be helpful?

TABLE 22 Interview schedules (*continued*)

Parents		
Big research question	Mini research question	Ways to approach this question
	How could study findings be effectively disseminated?	Are they interested in dissemination of study findings? To whom? Staff? Students? Parents? How do they think dissemination would be most effectively performed?

Appendix 5 Scoring system for numeric scales

TABLE 23 Scoring system for numeric scales

Questionnaire	Scale/subscale details	Question scoring	Overall score	Notes
A-SAQ	Single question with a choice of six responses to indicate levels of harmful drinking	1. never 2. < 4 times 3. ≥ 4 times but not every month 4. ≥ 1 per month but not every week 5. Every week but not every day 6. Every day	1–6	A score of ≥ 3 is considered a positive score for possible hazardous or harmful drinking
AUDIT	Ten questions about drinking behaviour with five possible responses for q1–8, or three responses for q9 and q10	Score of 0–4 for q1–8, and 0, 2 or 4 for q9 and q10	0–40, for which scores from each question are added	An AUDIT score of ≥ 8 is considered to indicate possible hazardous or harmful drinking in adults. There is currently no agreed score to indicate hazardous or harmful drinking in adolescents
AUDIT-C	First three questions of the AUDIT	All questions are scored 0–4	0–12, for which scores from each question are added	An AUDIT-C score of ≥ 5 is considered to indicate possible hazardous or harmful drinking in adults. There is currently no agreed score to indicate hazardous or harmful drinking in adolescents
RAPI	Twenty-three questions about drinking behaviour, each with four possible responses	All questions are scored 0–3	0–69, for which scores from each question are added	Higher RAPI scores indicate more problematic drinking behaviour
WEMWBS	Fourteen questions to assess level of happiness and life satisfaction	Each question is scored 1–5	14–70, for which scores from each question are added	WEMWBS provides robust results for populations and groups with higher scores indicating higher levels of well-being. It has not yet been validated for monitoring mental well-being in individuals
TLFB-28	Quantitative estimations of daily alcohol consumption		Provides a variety of different estimations of individual consumption levels	The TLFB is a method for assessing recent drinking behaviour. Administered by a learning mentor, it involves asking young people to retrospectively estimate their daily alcohol consumption over a 28-day time period prior to the interview. We will specifically derive total alcohol consumed in a 28-day period, percentage of days abstinent, drinks per drinking day, and number of days drinking more than two units

Appendix 6 Proposed case diary for definitive study

Intervention Time Diary

Please tick the appropriate boxes below



1. Approximately how long did you spend preparing for the intervention?

(i.e. studying file, setting appointment, locating young person, etc.)

- ☐ 0-5 mins ☐ 6-10 mins ☐ 11-20 mins ☐ 21-30 mins
☐ 31-45 mins ☐ 45+ (please write time) _____

2. Approximately how long did you spend with the young person delivering the intervention? (i.e. explaining intervention, delivering the intervention, etc.)

- ☐ None student withdrawn ☐ 0-10 mins ☐ 11-20 mins
☐ 21-30 mins ☐ 31-40 mins ☐ 41-50 mins
☐ 51-60 mins ☐ 60+ (please write time) _____

3. Approximately how long did you spend following-up after intervention?

(i.e. setting appointment with young person, locating young person, meeting, etc.)

- ☐ None student withdrawn ☐ 0-10 mins ☐ 11-15 mins
☐ 16-25 mins ☐ 26-35 mins ☐ 36-45 mins
☐ 46-60 mins ☐ 60+ (please write time) _____

A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and flow.

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