Randomised trial evaluation of the In:tuition programme

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Key findings for the primary school trial

- The primary outcome was resistance skills (confidence to manage peer pressure) in 10 and 11 year-olds. There was no evidence of any impact on this primary outcome.
- There was an indication of an effect of the intervention on increased knowledge (a secondary outcome). On average, primary pupils in the intervention group had slightly better knowledge about alcohol and its effects than those in the control group, although the results were not significant at the 0.05 level (p=0.07).
- There was no evidence of impact on other secondary outcomes.
- In terms of programme fidelity, of 40 schools randomised into the intervention group, only 15 were known to have delivered at least some of the intervention lessons.

Key findings for the secondary school trial

- The primary outcome was the proportion of students aged 12-13 that were drinking frequently. Overall, there was no significant effect on frequency of drinking.
- In the intervention group, males were more likely and females were less likely to be frequent drinkers compared to their counterparts in the control group at follow up. However, there is insufficient evidence to assert this was a genuine effect of the intervention.
- There was no evidence of impact on any secondary outcomes.
- Of 28 schools randomised into the intervention group, only five were known to have delivered *at least some* of the intervention lessons; only two secondary schools delivered all or most of the lessons.

Key findings from the process evaluation

- Perceived impacts of In:tuition on pupils included: increased knowledge and awareness of alcohol; development of strategies and skills to cope with potential social and emotional situations; and a change in projected future drinking.
- Teachers were positive about the programme content and teaching approaches but adapted the programme to take account of the time available and the needs/context of the school.

Background

This summary reports the findings from two cluster-randomised trials of Drinkaware's school-based In:tuition life skills and alcohol education intervention: one trial of the programme for 10-11 year olds in primary schools, and another for 12-13 year olds in secondary schools. The trials have been carried out by the National Foundation for Educational Research (NFER), funded and overseen by Alcohol Research UK using a grant provided by Drinkaware.

Although there has been a downward trend in consumption of alcohol amongst 11-15 year olds in England over recent years (Fuller, 2014), two-fifths (39 per cent) of young people in this age group have still drunk a whole alcoholic drink at least once; nine per cent of those have done so in the last week and five per cent usually drink alcohol once a week. The Government's Department of Education (DfE) recognises that effective drug and alcohol education is essential to tackling the problem of drug and alcohol misuse. Reviews of school-based alcohol misuse prevention programmes, including those undertaken by Foxcroft and Tsertsvadze (2011), Cairns et al. (2011) and Martin et al. (2013) have concluded that the evidence base for effective alcohol education programmes has been mixed.

The In:tuition intervention

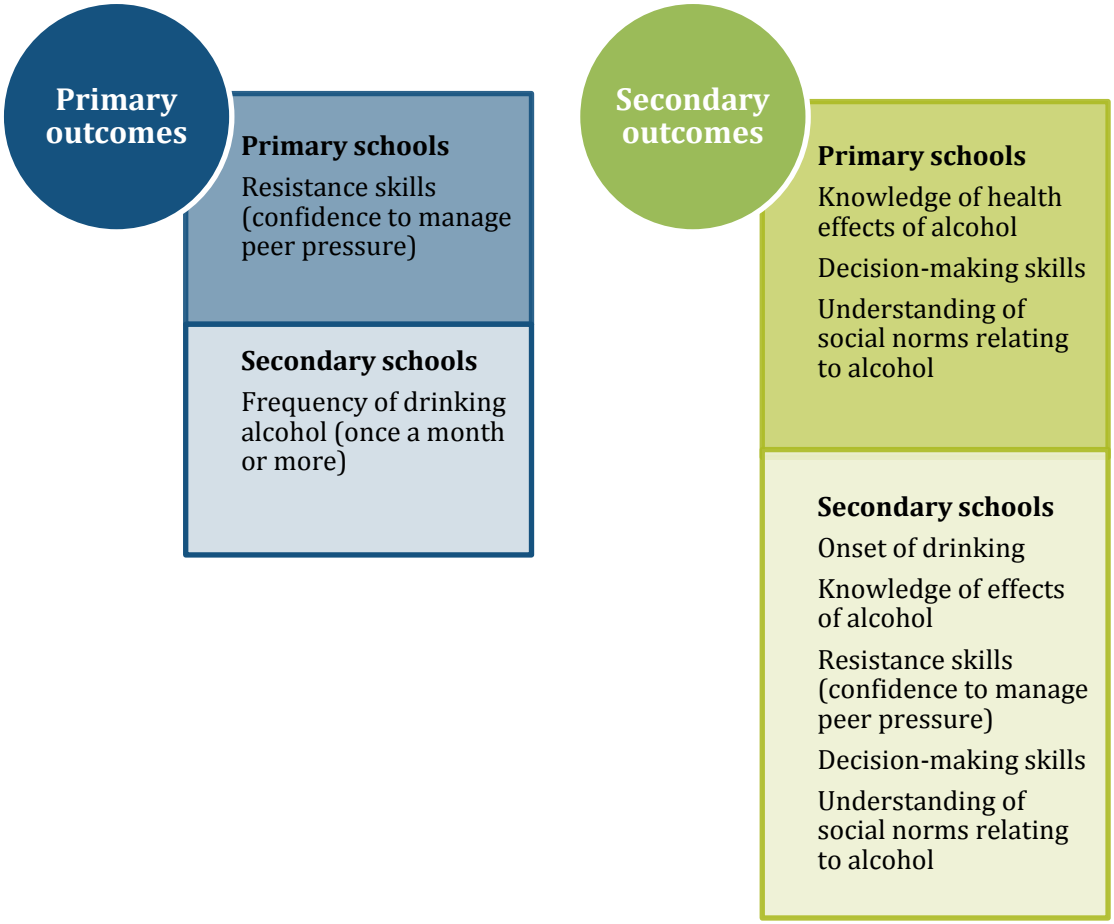
The development of the intervention was informed by evidence-based life skills programmes such as 'Unplugged' (see Faggiano *et al.,* 2010). However, there are differences between the programmes and the measures of impact that mean the results are not directly comparable. Alcohol is the main theme of the intervention, but its focus is wider and includes, for example, attitudes and behaviour, the influence of peers, communication skills and assertive behaviour. The main aim of the programme is to delay the age of first alcoholic drink.

The primary and secondary programmes each consist of 12 lessons (a period of 40 minutes is recommended for each lesson). Home learning tasks are included to encourage discussion with parents/carers. To access the programme, a user needs to register on the website. A helpdesk is available via the site. Lesson *content* is different for primary and secondary schools and, therefore, two separate trials have been implemented. A feasibility study was carried out in 34 schools across the UK (Barksfield and Hull, 2012). The trials were commissioned following this feasibility study.

Aims of the trials

The overarching aim of both trials was to evaluate the process and impact of implementing In:tuition in schools. The primary outcomes (those of greatest importance) and secondary outcomes (possible additional effects of the

programme) were linked to the main aims of the intervention and are illustrated below.



Methods

Schools were randomly allocated to receive the In:tuition intervention or to a 'business-as-usual' control. The trials compared any change over time between groups by carrying out a self-report questionnaire survey of students at two time points across two school years: before the intervention was implemented (June-September 2013) and after (June-July 2014).

The definitive analysis for the trial was an 'intention-to-treat' analysis, which includes all students who completed a questionnaire at both time points, regardless of the extent of In:tuition delivery (all intervention schools are treated the same). This represents how delivery might occur in a real-world scenario. To assess any differential impact by pupil characteristics, we conducted sub-group analysis in relation to primary outcomes using interaction terms. In addition, 'on-treatment' analysis was carried out, which accounts for differences in programme delivery.

A process evaluation, involving interviews with staff and pupils in nine case-study schools and a teacher survey, was carried out to explore programme implementation.

Sampling, recruitment and randomisation

For the primary school trial the aim was to recruit 70 schools in England containing Years 5 and 6. In total, 79 primary schools were recruited (after randomisation, 40 intervention schools and 39 control schools).

For the secondary school trial the aim was to recruit 80 schools in England containing Years 7 and 8. In total, 55 secondary schools were recruited (after randomisation, 28 intervention schools and 27 control schools).

Initially, schools were randomly selected from a sampling frame of 33 local authorities (LAs). It was then necessary to draw two top-up samples of new LAs, leading to a total of 55 LAs and 808 primary schools and 1513 secondary schools to achieve the obtained response. Schools that did not agree to participate were asked for feedback on the reasons why, although the majority said they were 'unable to help' and did not give specific reasons relating to concerns about the trial or intervention. Difficulties with recruitment *could* have been due to In:tuition's focus on life-skills and alcohol education, which are likely to be given less of a priority in schools compared with 'core' subjects, such as mathematics, English or science (due to timetable and curriculum pressures).

Schools in the control group were prevented from registering on the site during the course of the trial, but were given access at the end.

Results from the primary school trial

Of the 79 primary schools randomised (into 40 intervention schools and 39 control schools), there was some attrition before follow-up. A total of 24 intervention schools and 31 control schools completed both baseline *and* follow-up surveys. This yielded data from 723 intervention and 1019 control pupils for the final analysis. Comparisons of their characteristics suggested that the final intervention and control groups of primary pupils can be regarded as equivalent.

Of the 40 primary schools randomised into the intervention group, only 15 were *known* (based on information provided) to have delivered at least some of the intervention lessons. Little information was received about why some schools had agreed to participate and then either officially withdrew or went on to not deliver lessons. The issues of attrition and programme fidelity are likely to have an impact on the measurable effects of the intervention.

There is no evidence that the In:tuition programme improves the primary outcome of resistance skills (confidence to manage peer pressure in 10 and

11 year-olds). No significant differences were evident between the intervention and control groups and there was no effect on any sub-groups.

There was an indication of an effect of the intervention on the knowledge of primary pupils. The results show that, on average, those in the intervention group had slightly better knowledge about alcohol and its effects than those in the control group, although the results were not significant at the 0.05 level (p=0.07).

There was no significant difference between the groups in terms of their self-reported decision-making skills. Pupils in the intervention group were found to be no more likely to understand social norms relating to alcohol (that most people will not have a whole alcoholic drink before they are age 16) than those in the control group

Results from the secondary school trial

Of the 55 schools randomised (into 28 intervention schools and 27 control schools), there was attrition prior to follow-up, particularly for the intervention group. A total of 12 intervention schools and 15 control schools completed both baseline and follow-up surveys. This yielded data from 586 intervention and 814 control pupils for the final analysis. A comparison of their baseline characteristics yielded imbalance in two variables, neither of which were significant predictors of the primary outcome.

Of the 28 secondary schools randomised into the intervention group, only five were *known* to have delivered at least some of the intervention lessons; only two delivered all or most of the lessons. Again, little information was received about why some schools had agreed to participate and then either officially withdrew or went on to not deliver lessons. As for the primary school trial, the issues of attrition and programme fidelity are likely to have an impact on the measurable effects of the intervention; these issues were most prevalent among secondary schools.

There was no evidence that participation in the In:tuition programme had an impact on the primary outcome relating to the proportion of students overall aged 12-13 who were drinking frequently. However, males were more likely and females were less likely to be frequent drinkers compared to their counterparts in the control group at follow up. There is insufficient evidence though to assert this was a genuine effect of the intervention.

Although the proportion of pupils that had had an alcoholic drink by the time of the follow up survey was slightly higher in the intervention group than the control group, this difference was not statistically significant. Nor was there any significant difference between the intervention and control groups in relation to the other secondary outcomes.

Results from the process evaluation

Overall, most case-study teachers reported a range of *perceived* impacts on pupils, including increased knowledge and awareness, development of strategies and skills and modified behaviour. However, they felt that they would have achieved the same impact using existing provision.

Teachers were positive about the content and teaching approaches but adapted the programme to take into account the time available, the needs/context of the school, content covered in other lessons and pupils of different abilities in their class. Suggestions for improvements included:

- reducing the duration and content of the programme
- providing different formats to deliver the resources such as slides and more visual resources
- greater differentiation of content for pupils with lower levels of literacy
- pupils would like more opportunities for discussion and more pupil led activities.

Limitations of the trials

There were a number of limitations to these trials which could have had an impact on results:

- the level of measurement attrition, particularly in secondary schools
- the nature of the data obtained to conduct analysis on programme fidelity
- the programme materials being made available to schools later than expected, which could have impacted on fidelity
- the involvement of NFER staff in reminding schools to register for the intervention, which would not happen in the real world
- schools included in the process evaluation were those willing to take part (and thus are likely to be those most engaged with the programme).

Conclusions

To conclude, recruitment difficulties were faced, which was followed by school attrition (particularly in secondary schools) which could have had an impact on results. There was little evidence of positive – or indeed negative - impact of the programme. Pupils in schools which delivered the intervention did no better – or worse – than those in schools doing their normal Personal, Social, and Health Education (PSHE) curriculum. Evidence from the fidelity analysis and process evaluation indicates that not all teachers in the intervention group delivered the programme in its entirety – indeed some did

not deliver it at all. Moreover, the extent to which In:tuition was delivered in schools did not impact on this result. Although teachers saw some value in the individual elements of the programme, for the programme to have a positive impact in its *entirety* it needs fundamental revision.

1. Introduction

This report summarises the findings from two cluster-randomised trials of Drinkaware's school-based In:tuition programme: one trial of the programme for 10-11 year olds in primary schools, and another for 12-13 year olds in secondary schools. The two trials were registered as follows:

http://www.controlled-trials.com/ISRCTN86224191
http://www.controlled-trials.com/ISRCTN71372913

The trials have been carried out by the National Foundation for Educational Research (NFER), funded and overseen by Alcohol Research UK using a grant provided by Drinkaware. During the trials, schools were randomly allocated to receive In:tuition or to a 'business-as-usual' control. The trials compared any change over time for intervention and control groups by carrying out a self-report questionnaire survey of pupils at two time points across two school years: June-September 2013 and June-July 2014.

1.1 Policy background

Although there has been a downward trend in consumption of alcohol amongst 11-15 year olds in England over recent years (Fuller, 2014), there remains cause for concern. Two-fifths (39 per cent) of young people in this age group have drunk a whole alcoholic drink at least once; nine per cent of those have done so in the last week and five per cent *usually* drink alcohol once a week. Alcohol consumption increases with age amongst this population; six per cent of 11 year olds have ever had an alcoholic drink, which increases to 72 per cent by age 15 (a fifth of 15 year olds have had an alcoholic drink in the last week).

The Chief Medical Officer for England's official guidance on alcohol aimed specifically at young people (Donaldson, 2009) recommends that the best option is for children to remain alcohol free up to the age of 15; these statistics show that for a considerable proportion of young people aged 11-15 this is not the case. The 2012 Alcohol Strategy (HM Government, 2012) includes a commitment to sustain the reduction in the number of 11-15 year olds drinking alcohol.

There are health and societal risks associated with alcohol consumption. Annual statistics for young people's substance misuse interventions 2012-13 have recently been published by Public Health England[1] (2013), with 4,704 young people under 18 (24 per cent of the total) having approached specialist services with a concern centred around alcohol. In England, the

1Public Health England is the national agency for protecting and improving the nation's health and wellbeing and tackling health inequalities.

Health and Social Care Information Centre (2014) statistics on the costs and ill health associated with alcohol consumption showed that, in 2012-13, there were an estimated 1,008,850 hospital admissions related to alcohol consumption where an alcohol-related disease, injury or condition was the primary reason for hospital admission or a secondary diagnosis. Moreover, in 2013, there were 183,810 items prescribed (in a primary care setting or NHS hospital) for the treatment of alcohol dependency and dispensed in the community. The cost of these prescription items in 2013 was £3.13 million. One of Public Health England's priorities is 'helping people to live longer by reducing preventable deaths from conditions such as heart disease, stroke, cancer and liver disease' (Hoskins, 2013), to which excessive alcohol consumption can contribute.

The Government's Department for Education (DfE), which takes the policy lead for young people and alcohol, recognises that effective drug and alcohol education is essential to tackling the problem of drug and alcohol misuse. In March 2013, the DfE published outcomes of its review of Personal, Social, and Health Education (PSHE) (DfE, 2013), which emphasises the expectation for schools to use their PSHE programme to equip pupils with an understanding of risk and the knowledge and skills necessary to make safe and informed decisions. Yet PSHE remains a non-compulsory subject in England. Moreover, the official body for inspecting schools in England, Ofsted, identified weaknesses in PSHE relating to understanding of the physical and social damage associated with alcohol misuse and recommended that schools should ensure appropriate learning about these issues (Ofsted, 2013).

Reviews of school-based alcohol misuse prevention programmes, including those undertaken by Foxcroft and Tsertsvadze (2011), Cairns *et al.* (2011) and Martin *et al.* (2013) have concluded that the evidence base for effective alcohol education programmes has been mixed.

The Martin *et al*. (2013) review was carried out by NFER on behalf of Alcohol Research UK to give context to the trials of In:tuition reported here. They concluded that there have been difficulties in judging impact of school-based alcohol misuse prevention programmes due to the challenge of generalising about effective programme ingredients and issues related to programme fidelity (if fidelity has not been investigated through a thorough process evaluation, it is difficult to ascertain whether outcomes are a result of the effectiveness of the programme, or of the way in which it has been implemented). Their review found substantial evidence relating to the positive effects of school-based alcohol education and life-skills programmes on pupils' alcohol related-knowledge but variable and inconclusive findings in relation to pupils' attitudes towards drinking and their decision-making skills. They found a degree of evidence of the effectiveness of alcohol education and life-skills programmes in reducing the frequency of alcohol consumption and episodes of drunkenness among school-aged children. They noted, however, limitations to several of the research studies cited.

1.2 The In:tuition Intervention

Drinkaware is an independent alcohol education charity, funded through contributions from the alcohol industry. As part of its preventative work, Drinkaware has developed the In:tuition life skills education programme, targeted at young people aged 9-14. The main aim of the programme is to delay the age of first alcoholic drink. The primary and secondary programmes each consist of 12 lessons (a period of 40 minutes is recommended for each lesson). Alcohol is its theme but the focus is much wider and also includes:

- self-awareness
- attitudes and behaviour
- advertising, branding and the media
- personal choices
- emotions, communication skills and assertive behaviour
- the influence of peers
- goal setting and confidence.

A full description of the lessons included in the primary and secondary programmes is given in Appendix A. In:tuition uses a 'life skills approach' to help pupils learn and practice some important skills such as communication, working as a team and decision-making. The programme can be delivered through Personal, Social, and Health Education (PSHE) and Citizenship teaching but schools can also adopt a cross-curricular approach. Some digital tools are included, but each lesson has a paper-based alternative available to download. Home learning tasks are included to encourage discussion with parents/carers and promote consistent messages to young people at home and school. To access the programme, a member of school staff needs to register on the website and is issued with a verification password. A helpdesk is available via the site, should users have any queries.

The programme was been developed by Drinkaware in partnership with ICE Creates. The evaluators have had no involvement in the programme design and are therefore entirely independent. Furthermore, a policy was instigated by Alcohol Research UK (who managed the evaluation) stipulating that members of the evaluation team should not communicate with the programme developers (either ICE Creates or Drinkaware) unless a representative from Alcohol Research UK was present or copied in to emails.

Although the *structure* of the programme is consistent for primary and secondary schools, lesson *content* is different. The delivery contexts in primary and secondary schools are also likely to vary. Therefore, two separate trials have been implemented and the outcomes are reported separately.

1.3 Background evidence

The development of In:tuition was informed by evidence-based life skills programmes such as 'Unplugged', a school-based drug prevention programme for pupils aged 12-14 years which was trialled and evaluated in seven EU countries (see European Drug Addiction Prevention, 2007 and Faggiano *et al.,* 2010). Note, though, that there are differences between the programmes, including content (Unplugged covers the broader issues of tobacco and illicit drugs) and the fact that the Unplugged programme incorporates two and a half days of training for teachers who will deliver it. In addition, the outcomes measured in the trial of Unplugged were not directly comparable to those being measured in the trial of In:tuition (because the primary outcomes were deemed to be different due to programme content) and therefore results are not directly comparable.

In 2011-12, CSN was commissioned by Alcohol Research UK to carry out a feasibility study and process evaluation in 34 schools recruited from across the UK (18 primary schools, 3 middle schools and 12 secondary schools). The study (Barksfield and Hull, 2012) investigated the implementation of the programme in the classroom, the extent to which it was implemented as intended, its acceptability to staff and pupils, its relevance and appropriateness, barriers to implementation and any requirements for additional support or training. A number of recommendations were made as a result of the study, including:

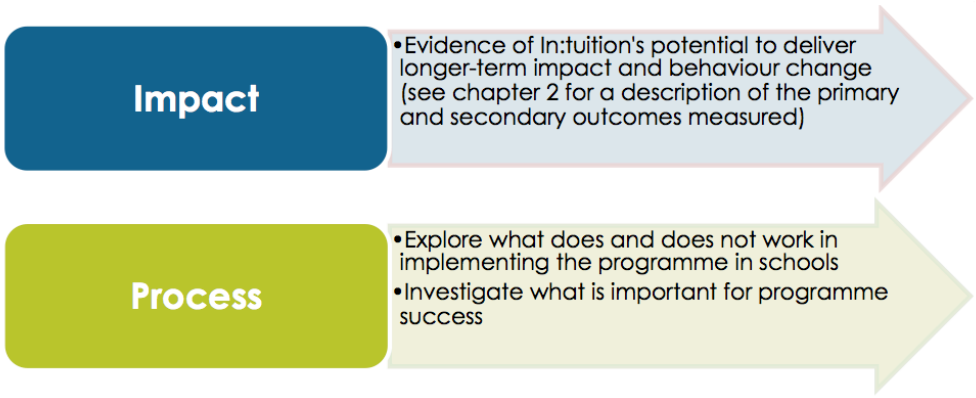
- taking steps to encourage better course fidelity, which could be assisted by reducing the number of digital tools, identifying a variety of curriculum models and, where possible, reducing the length of the programme
- promoting In:tuition as a core life skills course rather than an alcohol resource based on a life skills approach
- making any digital tools that remain in the programme more accessible
- encouraging parental engagement with the 'home learning' activities.

Following the feasibility study, Drinkaware invited Alcohol Research UK to commission trials of an amended programme. Following an open application process, NFER was selected by Alcohol Research UK to conduct a randomised control trial and second-stage process evaluation of the revised programme. Note that NFER was commissioned as the programme revisions were being made. This meant that schools agreed to participate before seeing the materials (although an explanation of their content was given). Details of the trial can be found in the following sections.

1.4 Trial objectives

Alcohol Research UK commissioned trials to provide evidence, if any, of In:tuition's potential to deliver longer-term impact and behavioural change and to ensure that any future programme development was based on a thorough understanding of what does and does not work and why that is important to programme success. With this is mind, the overarching aim of both the primary and secondary school trials was to evaluate the process and impact of implementing In:tuition in schools; see Figure 1.

Figure 1: Aims of the trials



The **main hypotheses** were:

- **Primary school trial**: the use of the In:tuition programme improves resistance skills (confidence to manage peer pressure) in 10 and 11 year-olds
- **Secondary school trial**: participation in the In:tuition programme has an impact on the proportion of pupils aged 12-13 that are drinking frequently

The primary and secondary outcomes measured in order to address these and other related hypotheses are listed in Chapter 2, along with a description of the trial methods.

2. Trial and Analysis Method

The primary and secondary school trials adopted a cluster-randomised design, whereby schools were recruited to the trial and then randomised either to receive the In:tuition programme or not – thus becoming intervention and control groups respectively (schools were made aware at the time of recruitment that they would be randomised into either group). Control schools continued with their normal PSHE/alcohol education curriculum.

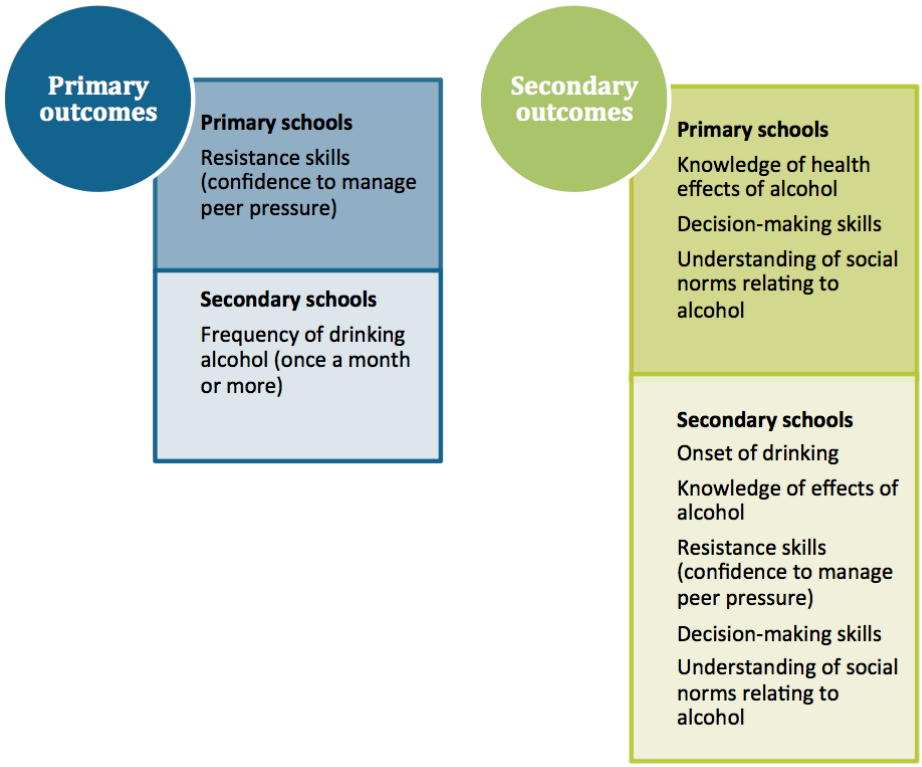
Further details of the trial methodology (including eligibility, sampling and recruitment and randomisation) can be found in the primary school trial and secondary school trial sections that follow (3.1 and 4.1).

2.1 The outcomes

The primary outcomes (those of greatest importance) and secondary outcomes (possible additional effects of the programme) are illustrated in Figure 2. The two primary outcomes reflect the main aims of the programme at the different phases. The main long-term goal of both primary and secondary school programmes was an impact on young people delaying the age of their first alcoholic drink and a reduction in regular drinking. For primary schools, the more immediate goal (as few pupils are drinking alcohol) was better understanding of strategies that can be used to help make responsible choices and confidence to manage peer pressure (resistance skills; the primary outcome of the trial). At secondary school age, it is more possible to measure current drinking behaviours and therefore the primary outcome was frequency of drinking. The secondary outcomes reflect the other key aims of the programme at both phases.

The outcomes and sub-group analyses were agreed with stakeholders before baseline measurement took place. Outcome measures are explained in Appendix B.

Figure 2: Outcome measures



2.2 The research instrument

The evaluation instrument was a self-report questionnaire survey of pupils administered at two time points across the school years 2012-13 and 2013-14. At both time points, the survey was available on paper and online. The questionnaire was identical at both time points. The surveys were designed to be age-appropriate, including questions assessing pupil characteristics and questions relating to the primary and secondary outcomes (see below) and other topics covered in the In:tuition programme. Where possible, a variety of tried and tested questions were included.[2] Some new questions were designed and piloted in a local primary school and amended slightly on the basis of discussion with pupils about how they had interpreted questions. The final instrument consisted of closed questions, where respondents were required to select a response or enter a number. The survey was completed by schools at different times during a short survey period (June-July 2013 and September 2013[3]), rather than simultaneously, in order to give schools flexibility with their timetables. At baseline stage, pupils' names were collected from the questionnaires and retained for the administration of the

2 Including questions used in the annual survey of smoking, drinking and drug use among young people (Fuller, 2013) and the evaluation of the Talk About Alcohol materials (Lynch et al., 2013).
3 A flag was added to the final analysis to indicate the timing difference in the administration of the baseline survey, which could have an impact on outcomes.

final survey in summer 2014. Pupils were reassured that surveys are confidential and that their names are not shared outside of the research team.

2.3 Analysis method

For both the primary and secondary trials, the 2014 and 2013 survey datasets were matched so that each pupil had one record with variables for each of the outcomes at baseline and follow up (but just single variables for pupil characteristics as these remain constant).

2.3.1 An 'intention-to-treat' (ITT) analysis

Intention-to-treat (ITT) analysis includes all pupils who completed a questionnaire at both time points, regardless of treatment attrition (i.e. the extent of In:tuition delivery). This means that the fact that some schools might not have delivered the programme as intended is ignored in 'intention-to-treat' analysis and all intervention schools are treated the same. This was the definitive analysis for the trial as it represents how delivery might occur in a real-world scenario. Furthermore, it avoids bias that might ensue by excluding intervention schools that have not delivered the programme. Such schools could share certain characteristics that make them less amenable to positive outcomes; excluding them could therefore favour the intervention group.

2.3.2 On-treatment analysis

This analysis accounts for differences in programme delivery to determine any association between 'programme fidelity' (how many lessons of In:tuition were actually delivered) and the outcomes of interest.

Due to issues with intervention fidelity during the trial, an 'on-treatment' analysis of this type is particularly vulnerable to bias i.e. the schools that have delivered the programme as intended are likely to share certain characteristics that might influence the outcome. The results of this analysis cannot therefore be considered causal. During the trial, it became apparent through communications with schools that the intervention was not being delivered as intended (see later in the report for details) and, particularly in secondary schools, was not always being delivered at all. We therefore proposed an additional quasi-experimental analysis for secondary schools to compare outcomes for pupils who have experienced the intervention with similar pupils in the control group who have not. It transpired that only two secondary schools delivered all or most of the lessons so this analysis was not possible in the end.

Information on the extent of programme delivery in schools was obtained from a number of sources: the programme developers ICE Creates (based on

output from the In:tuition website, which recorded the schools that had registered to access the materials and where *some* users logged that they had delivered lessons); responses to a teacher questionnaire which asked which lessons had been delivered; and information volunteered by schools (i.e. during NFER contact with schools, some revealed that they had registered for the programme but had not gone on to deliver lessons).

2.3.3 Statistical modelling of primary and secondary outcomes

The most powerful and unbiased way to analyse the data from these trials, that contain measures from the same pupils at baseline and follow-up, is through a regression model of follow-up score using baseline score (and other predictors) as covariates. This is equivalent to ANCOVA and the reason for this being the best approach is discussed by Senn (2006). Since schools were randomised, rather than pupils, it was necessary to use a multi-level model to ensure standard error (and associated confidence intervals and p-values) was correctly estimated. Details of the models, including the covariates used, are given in Appendix F. For each model, the following procedure was adopted:

- covariates were checked for high correlation and excluded if deemed a risk of multicollinearity
- a 'base case' model was run using a two-level (pupil and school) multi-level model with no covariates. This returned the pupil-level variance for effect size calculation.
- the outcome was then modelled using a two-level (pupil and school) multi-level model containing all pre-specified covariates as measured at baseline that may have been influential. Significant variables were selected using backward selection.
- the resulting model was then re-run with intervention forced in (if necessary); the intervention coefficient was then used in effect size calculations.

2.3.4 Effect sizes

A standardised effect size has been presented in Appendix F. For the continuous outcomes, the effect size has been calculated as the coefficient on the intervention group indicator divided by the pupil-level standard deviation from a model with no covariates. For the logistic models (where the outcome is binary e.g. yes/no) we use the odds ratio as a standardised effect size measure. See Appendix C for information on effect sizes.

2.3.5 Confidence intervals

We have estimated a 95 per cent confidence interval alongside the standardised effect size to give the precision with which the effect size has been estimated. The upper and lower bounds of the confidence interval were calculated as the effect size plus/ minus the product of the critical value of the normal distribution (≈ 1.96) and the standard error of the group indicator coefficient estimated from the multilevel model.

2.3.6 Missing data

Measurement attrition (i.e. drop out from the trial between randomisation and endpoint measurements, and hence missing endpoint data) is a concern in this as in all trials. Missing baseline data is also an issue. Missing data can give rise to biased results as the reason for being missing could be related to the outcomes measured. Two strategies were employed to address this problem: comparisons of the baseline characteristics of analysed groups (see Table 3 for characteristics of primary pupils and Table 13 for characteristics of secondary pupils) and multiple imputation. Multiple imputation is a statistical technique that attempts to repopulate the dataset with reasonable values given other observed factors. Results of the multiple imputation were compared with those from the raw data alone in view of checking whether the original result was free from bias. Though complicated, the technique is a well established way to address possible bias that avoids the pitfalls of simpler, though commonly used, alternatives.[4]

2.3.7 Sub-group analysis

To assess any differential impact by pupil characteristics, we conducted sub-group analysis as part of the analysis of the primary outcomes only, using interactions. In each case, the final primary outcome model was re-run containing the sub-group variable and interaction term. The following characteristics were considered:

- gender
- ethnicity
- free school meals (self-reported)
- age in months
- siblings/eldest sibling
- religious group
- parental drinking in the home

[4] Commonly used alternatives include mean imputation, last observation carried forward or using a dummy variable in the model to identify missing cases.

- attitudes to school (a composite measure).

2.3.8 Family-wise error rate

Across both trials we have carried out a total of 28 statistical tests, if you include primary and secondary outcomes and sub-group analyses (more if you include on-treatment analysis). If these tests were all independent then the probability of at least one type I error (concluding the intervention has an effect when in fact it does not) is over 0.75. Across the secondary trial alone we have carried out a total of 15 statistical tests and with the same assumption, the probability of at least one type I error is just over 0.5. This emphasizes the importance of the primary outcome analysis: all other analyses are merely exploratory and would require further research to attribute a genuine effect.

2.4 Reporting

To construct this report, we used a draft version of CONSORT-SPI, a CONSORT Extension for social and psychological interventions, obtained from the guideline authors (Montgomery et al., 2013).

2.5 Ethical review

The NFER has a well-developed Code of Practice that contains detailed ethical protocols which govern all research undertaken by NFER. The trials were agreed by NFER's Code of Practice Committee in May 2013. The Committee also approved research instruments. Letters were sent to parents enabling them to withdraw their child from the trials (see Appendix D).

3. The Primary School Trial

Key findings

- **Primary outcome: resistance skills -** there is no evidence that the In:tuition programme improves confidence to manage peer pressure in 10 and 11 year-olds. No significant differences were evident between the intervention and control groups and there was no effect on any sub-groups.
- **Secondary outcome: knowledge -** the results show that pupils in the intervention group were slightly more likely to have better knowledge about alcohol and its effects than those in the control group, although the results were not significant at the 0.05 level (p=0.07).
- **Secondary outcome: decision-making skills** – there was no significant difference between the groups in terms of their self-reported decision-making skills and, therefore, no evidence that In:tuition has an impact on how pupils make decisions about staying safe and minimising risk.
- **Secondary outcome: understanding social norms relating to the proportion of young people who drink alcohol** – pupils in the intervention group were found to be no more likely to understand the fact that most other pupils have *not* had a whole alcoholic drink
- **Fidelity:** Of the 40 schools randomised into the intervention group, only 15 were known to have delivered at least some of the intervention lessons (note that three schools officially withdraw from the trial and another three schools did not participate in the baseline survey).

3.1 Methodology

Trial Design

The trial adopted a cluster-randomised design, whereby primary schools were recruited to the trial and then randomised either to receive the In:tuition programme or not – thus becoming intervention and control groups respectively (schools were made aware at the time of recruitment that they would be randomised into either group). Control schools continued with their normal PSHE/alcohol education curriculum. Intervention and control groups were equal in size.

The trial was designed as an 'effectiveness' trial; with every attempt to mirror how In:tuition might be delivered for real. Schools were recruited from a large national sample and had minimal assistance with intervention delivery. However, due to few schools registering on the In:tuition website, the evaluator agreed in the early stages of the trial to start assisting schools with

the registration process. The trial thus became an 'efficacy'[5] trial as the level of assistance that schools received is unlikely to be matched in a real-world delivery scenario.

Eligibility

Primary schools in England containing Years 5 and 6, in an agreed sampling frame of local authorities (see below), were eligible for the trial. This included maintained schools, academies, free schools, pupil referral units and independent schools. Special schools and schools which had already registered to use the In:tuition programme were excluded.

Sample size

A total of 70 schools for randomisation to two groups of 35 was deemed a sufficient sample size to detect an effect size of 0.15. Lynch et al. (2012) saw a quasi-effect size of 0.17 in terms of knowledge outcomes after a similar-length intervention. Sample size calculations assumed an intra-cluster correlation of 0.1 (conservative for attitudinal outcomes controlling for baseline), a correlation between baseline and follow-up of 0.8, an effect size of 0.15, power of 0.80 and 25 pupils per school. The average size of a year group at primary school in the UK is 36. However, we have based our calculations on a school size of 25 since the geographical constraints of the trial may have partially restricted the sample to one-form entry schools.

Sampling and recruitment

For the primary trial the *aim* was to recruit 70 schools for randomisation to intervention and control groups. If a school signed up, all pupils in Year 5 were recruited to the trial. Schools were randomly selected from a sampling frame of 33 local authorities (LAs) agreed with ICE Creates (one of the programme developers). Authorities were selected in geographical clusters in order to retain other areas for future evaluation of In:tuition. Schools were excluded if they were already registered with ICE Creates. The sample was stratified by region and percentage of pupils eligible for free school meals. The initial recruitment strategy was to draw large samples of schools, predicting that recruitment might be difficult (our experience is that research projects relating to life-skills and health-related subjects are often given less of a priority in schools than those relating to other 'core' subjects, such as mathematics, English or science). Indeed, to achieve the required response,

[5] Efficacy trials aim to determine whether an intervention can work under ideal or developer-led conditions. Effectiveness trials aim to determine whether an intervention can work at scale, usually in a larger number of schools, where assistance with delivery reflects what is possible in a roll-out scenario.

it was necessary to draw two top-up samples of new LAs and schools, in addition to the original sample. These consisted of 14 and 8 LAs respectively. This was despite reminder strategies, which included sending letters with information about the trial and the intervention, as well as sending faxes, emails and a telephone reminding campaign. The final complete sampling frame of LAs is presented on a map in Appendix E. In total, 79 schools were recruited (see Section 3.2.1 for details). The total number of primary schools invited to take part to recruit 79 schools for the primary trial was 808 across 55 LAs.

We sought feedback from schools which did not wish to be included in the trial, but despite contacting schools on numerous occasions did not always receive a response. A total of 94 primary schools gave feedback, but it was not always specific (see Table 1 below).

Table 1: Reasons for initial non-participation in the primary school trial

Reason	Number of Schools
Non-specific; unable to help	83
Lack of time	4
Involved in other projects	3
Staff changes/shortages	2
Did not feel programme content was appropriate	1
School circumstances	1
Total = 94	

Due to the difficulties with recruitment the baseline survey period was extended from the summer term 2013 into September 2013. These circumstances meant that the questionnaires were completed by schools at different times during a survey period that included June-July 2013 and September 2013[6].

Randomisation

Randomisation took place in the summer term 2013 during June and July. Once recruited, the 79 schools were allocated randomly to intervention or control groups, then informed of their group allocation and asked to complete the baseline questionnaire. Schools in the control group were prevented from registering on the site during the course of the trial, but were given access at the end.

[6] A flag was added to the final analysis to indicate the timing difference in the administration of the baseline survey, which could have an impact on outcomes.

Randomisation was carried out by an NFER statistician using a full syntax audit trail within SPSS v21. Two adjustments were made to the ideal randomisation process. Firstly, rather than the complete group of recruited schools being randomised together, schools were randomised in five blocks as and when a sufficient number had been recruited. Block sizes were 46, 12, 10, 10 and 1. Secondly, schools were aware of their group allocation when they completed the baseline questionnaires, as they were simultaneously notified of their group and asked to complete questionnaires. Ideally they would be blind to group allocation at this stage to minimise bias so this may have affected the results or response rates. For example, schools could have opted to complete or not complete the baseline questionnaire based on group allocation.

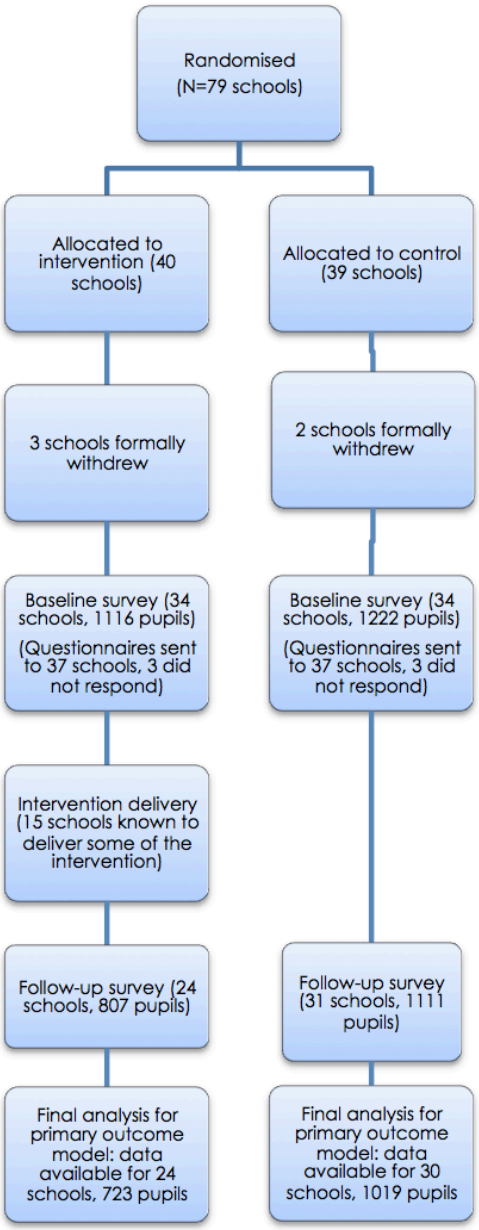
This approach was adopted mainly to facilitate schools' participation in the trial. Schools were understandably keen to know which group they had been allocated to as soon as possible so that if necessary they could plan for delivering the intervention the following term. Due to the number of lessons within the In:tuition programme, timetabling was a particular challenge for schools so they needed as much notice as possible. In addition, recruitment took place over a period of several weeks over the summer term 2013. Communication with schools needed to take place as early as possible due to the summer holidays. It was determined that it was more efficient and practical to inform schools of their allocation and ask them to complete questionnaires simultaneously.

3.2 Results for the Primary School Trial

3.2.1 Participants

As shown in Figure 3, a total of 79 schools were recruited and randomised into 40 intervention schools and 39 control schools.

Figure 3: primary school trial



3.2.2 Attrition and exclusions

As shown in Figure 3, following randomisation, three intervention and two control schools formally withdrew prior to the baseline survey, leaving 37 in each group (including 37 in the intervention group expected to register to deliver the In:tuition programme). A total of 34 schools in each group then completed baseline surveys, yielding data from 1116 intervention pupils and 1222 control pupils (a total of 2338) in Year 5 (age 9-10).

3.2.3 Participants in the end-point survey

A total of 74 schools were included in the sample for the follow up survey – these included all schools which were recruited at baseline and sent questionnaires (regardless of whether they completed them) and excluded the five schools which actively withdrew from the trial at baseline. A further three schools actively withdrew from the end-point survey (two intervention schools and one control school). The number of schools completing both baseline *and* follow-up surveys was 24 intervention schools and 31 control schools. The number of pupils completing *both* surveys was 727 intervention and 1027 control pupils (although they did not all necessarily answer all questions).This is slightly larger than the number included in the primary outcome analysis as the latter required pupils to have a full complement of data from the relevant variables.

Table 2 shows the characteristics of the primary *schools* included in the primary outcome analysis compared with the population of LAs from which schools were drawn. There were no significant differences between the final analysed sample and the population for region and percentage eligible for free school meals (FSM). This suggests that within the final sample we have a spread of schools that reflects the population from which they were drawn, at least in terms of these two variables.

Table 2: Primary school profile at follow up survey

		Population		In sample	
		Number	**%**	**Number**	**%**
Government Office Region	North East	633	16	11	20
	North West/Merseyside	604	15	11	20
	Yorkshire & The Humber	541	14	8	15
	West Midlands	449	11	5	9
	South East	1136	29	11	20
	South West	625	16	8	15
Total N=		3988		54	
% students eligible for FSM 2010/11 (5 pt scale)	Lowest 20%	623	17	10	19
	2nd lowest 20%	755	21	13	25
	Middle 20%	793	22	8	15
	2nd highest 20%	814	22	11	21
	Highest 20%	690	19	11	21
Total N=		**3675**		**53**	

Table 3 shows the baseline characteristics of pupils for whom data was collected at baseline *and* follow up. A school-level comparison between the intervention and control group means identified any imbalance between the groups in terms of the measured baseline characteristics. None of the comparisons revealed statistically significant differences, which suggests that the final intervention and control groups of primary pupils can be regarded as equivalent. Cases with particular characteristics were not more likely to have dropped out i.e. we had no biased attrition in the variables measured.

Table 3: Baseline characteristics of primary school pupils[7]

Covariate	Group	Number of Schools	Number of Pupils	Mean	P-value
Resistance skills at baseline	Control	30	1019	2.94	0.725
	Intervention	24	723	2.83	
Surveyed after July	Control	30	1019	0	0.111
	Intervention	24	673	0.08	
Age at test in months	Control	30	1013	123.66	0.572
	Intervention	24	720	123.43	
Self reported free school meals	Control	30	987	0.28	0.169
	Intervention	24	697	0.20	
Boys	Control	30	1019	0.51	0.483
	Intervention	24	723	0.49	
Ethnicity non white	Control	30	1019	0.11	0.395
	Intervention	24	723	0.08	
Ethnicity unknown	Control	30	1019	0.75	0.836
	Intervention	24	723	0.08	
Number of siblings	Control	30	978	2.15	0.622
	Intervention	24	698	2.25	
Eldest child	Control	30	988	0.38	0.758
	Intervention	24	705	0.37	
Never drink in home	Control	30	1019	0.19	0.653
	Intervention	24	723	0.17	
Often drink in home	Control	30	1019	0.11	0.499
	Intervention	24	723	0.10	
Christian	Control	30	1019	0.32	0.538
	Intervention	24	723	0.36	
Other religion	Control	30	1019	0.05	0.795
	Intervention	24	723	0.06	
Religion unknown	Control	30	1019	0.14	0.347
	Intervention	24	723	0.17	
Attitude towards school (composite variable from Q7)	Control	30	1019	29.10	0.605
	Intervention	24	723	29.0	
Independent or Academy school	Control	30	1019	0.13	0.570
	Intervention	24	723	0.08	
% pupils eligible for free school meals (2012/13)	Control	30	1008	19.52	0.536
	Intervention	24	723	16.83	
KS2 overall performance band 2013 (average point score)	Control	30	945	2.78	0.372
	Intervention	24	683	3.13	

[7] *'Surveyed after July' represents a flag that identifies schools that administered their baseline survey in the autumn term. It has a mean value of zero for control schools as it so happens that no control schools were surveyed late.*

Primary schools from which data was collected at baseline *and* follow up[8] were grouped into one of four categories depending on the extent to which they were known to have completed the In:tuition programme. As shown in Table 4 below, only 15 of these primary schools delivered at least some of the lessons.

Table 4: Fidelity of primary intervention schools to the In:tuition programme

	Number of primary schools	
	Completed baseline only	**Completed baseline and follow up**
All or most lessons completed	8	8
6 or fewer lessons completed	7	7
Known to have completed no lessons (e.g. withdrew)	13	8
Known to have registered on the In:tuition website but number of lessons completed unknown	6	1
Total	34	24

Due to initial low registration rates on the In:tuition website, the following assistance was offered by the evaluator to intervention schools: the sending of an introductory guidebook, assistance with registration via telephone conversations and directing school staff to the ICE Creates helpline. Furthermore, ICE Creates was occasionally prompted to respond to helpline calls. It is not possible to say to what extent this external help altered fidelity but it meant that the trial represented a slightly exaggerated picture of how well schools might deliver the programme in reality.

Information on *why* schools did not go on to register or go on to deliver the lessons was limited, but indicates that challenges relating to staff shortages and/or limited time available on the timetable were the main factors.

The issues of attrition and programme fidelity outlined above are likely to have an impact on the measurable effects of the intervention.

[8] And therefore had pupils eligible for the ITT analysis

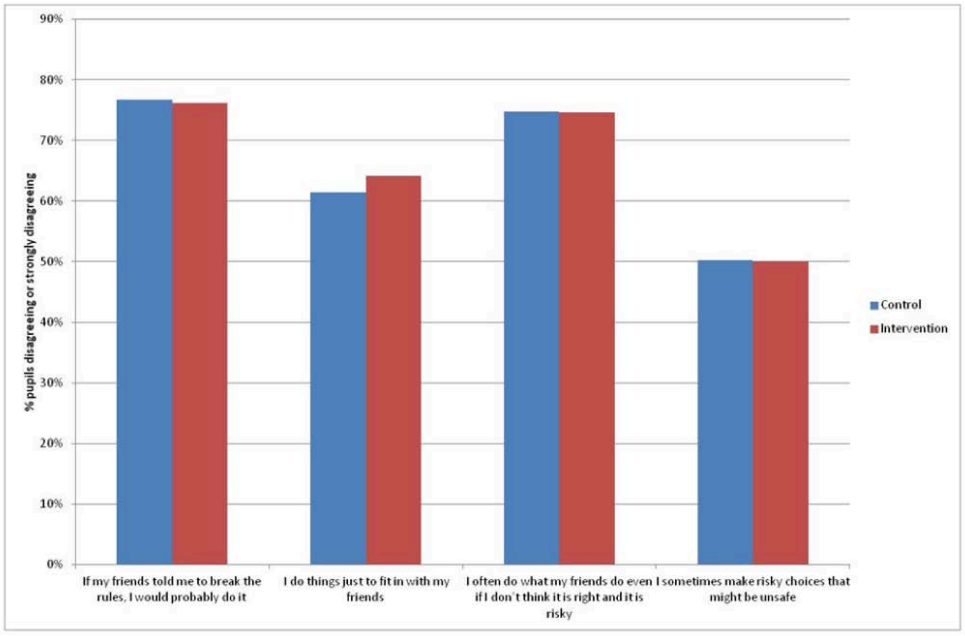
3.2.1 Results for the primary outcome: Resistance skills (confidence to manage peer pressure)

As outlined in Section 2.1, the main aim of the In:tuition programme in primary schools is to equip pupils with a better understanding of strategies that can help them make responsible choices and have the confidence to manage peer pressure (i.e. resistance skills). Therefore, 'resistance skills' was the primary outcome measured for the primary school trial, based on responses to the following questions:

- if my friends told me to break the rules, I would probably do it
- I do things just to fit in with my friends
- I often do what my friends do even if I don't think it is right and it is risky
- I sometimes make risky choices that might be unsafe.

At follow-up, primary school pupils tended to indicate that they were able to act independently of their friends, if they did not agree with what their friends were saying or doing (see Figure 4). Only a small minority of pupils in both groups (seven per cent) agreed that they would probably break the rules if their friends told them to. Furthermore only one in ten in both groups agreed that 'I often do what my friends do, even if I don't think it is right and it is risky' (nine percent of the intervention group and ten per cent of the control group). A slightly greater proportion, yet still a minority, agreed that they would do things just to fit in with their friends (16 per cent and 17 per cent respectively). An even greater proportion (yet this remained a minority) agreed that they sometimes made choices that might be unsafe (25 per cent of pupils in the intervention group compared with 28 per cent of control pupils).

Figure 4: Primary school pupils' resistance skills (follow-up survey)



From the results above, there did not appear to be a difference between the intervention and control groups. This was explored further with additional analysis. A score was derived from pupils' responses to the questions listed above (with a possible range from -8 to 8; see Appendix B for more details). Table 5 shows the mean scores for pupils across the intervention and control groups (for example, the mean score for pupils in intervention schools was 3.37).

Table 5: Mean scores for resistance skills

Outcome	Group	Number of schools	Number of pupils	Mean
Resistance skills at follow up	Control	30	1019	3.21
	Intervention	24	723	3.37

Statistical modelling was then carried out, which accounts for any differences between the intervention and control groups. The main analysis was an 'intention-to-treat analysis' (ITT; see Chapter 2 for details) to determine if there was a significant difference in resistance skills between the intervention and control pupils. Table 6 shows that there was **no significant difference** in resistance skills between pupils in intervention and control groups. Therefore, there is no evidence that the In:tuition programme improves confidence to manage peer pressure in 10 and 11 year-olds.

Table 6: Effect sizes for the 'resistance skills' (primary outcome) model and 'knowledge' and 'decision making skills' (secondary outcomes) models (continuous outcome variables, multi-level models)

Outcome description	Outcome measure	Effect size	95% confidence interval (lower)	95% confidence interval (upper)	p-value	Number of intervention pupils in model	Number of control pupils in model	Number of intervention schools in model	Number of control schools in model
Primary	Resistance Skills	0.05	-0.09	0.19	0.49	723	1019	24	30
Secondary	Knowledge of the effects of alcohol	0.17	-0.01	0.36	0.07	726	1022	24	30
Secondary	Decision making skills	-0.02	-0.16	0.12	0.78	727	1021	24	30

To investigate this finding further, the characteristics of pupils in the two groups at follow-up were explored to see if they can still be regarded as equivalent, at least in terms of outcomes we have measured. In this case, there was no evidence of imbalance between groups in baseline characteristics (see Table 3) and thus groups can be regarded as equivalent.

Additionally, multi-level multiple imputation of missing data (MI)[9] was attempted using variables that were present in the final primary outcome analysis model. Before running the MI model, measures that had been derived from a series of questions were classed as missing if *any* of the constituent questions were missing. For the main ITT analysis, they had only been coded missing if *all* constituent questions were missing; those that were missing being coded to the midpoint of the scale for the calculation of the measure. This change resulted in a loss of 209 cases and the raw coefficient for intervention altered slightly: from 0.164 (0.238)[10] to 0.146 (0.236). In order for the MI model to run, it had to be simplified to single level. After MI, the raw coefficient for intervention changed to 0.236 (0.159). Thus after MI the non-significant result was retained and, providing cases were missing at random given covariates, we can conclude that the result stands. MI was run in MLwiN (version 2.27) using macros downloaded from www.missingdata.org.uk.

To assess any possible differential impact on resistance skills by pupil characteristics, sub-group analysis was carried out on the ITT dataset introducing: gender; ethnicity; free school meals (self-reported); age in months; whether a pupil has siblings/is the eldest sibling; religious group; parental drinking in the home and attitudes to school (a composite measure) using interaction terms (i.e. interaction between the intervention and pupil characteristic). No significant effects of the programme on sub-groups were found.

The intention-to-treat analysis does not take into account the extent to which a school followed and completed the In:tuition programme, so additional, 'on-treatment' analysis was carried out to take into account the fact that **adherence to the programme**, or 'fidelity', had varied considerably between schools (also see Chapter 5, the process evaluation). The on-treatment analysis comprised of a multi-level model with the fidelity information added as covariates (see Appendix F for the output). There was no significant difference between the groups, therefore there is no evidence to show that teaching more of the In:tuition programme had an impact on pupils' resistance skills.

Further 'on-treatment' analysis was carried out to look at whether In:tuition had an impact on resistance skills **if pupils received the specific lesson on this topic** (lesson seven, 'What should I do?') (see Appendix F for the output). Although resistance skills and confidence are themes running throughout the programme, lesson seven was most relevant and only known to have been taught in eight of the primary schools.[11] There was no significant difference between the resistance skills of pupils that had received lesson seven, and those that had not.

[9] Multiple imputation is a statistical technique that attempts to repopulate the dataset with reasonable values given other observed factors.
[10] The standard error appears in brackets.
[11] Lesson data was not available for all schools

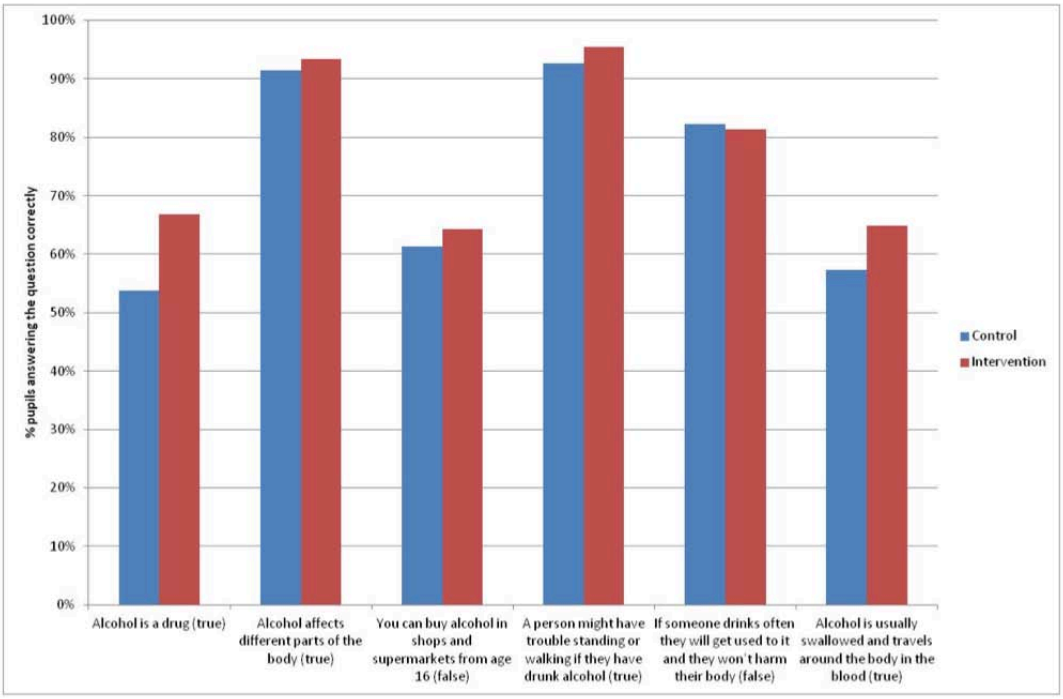
3.2.2 Results for the secondary outcome: knowledge about alcohol and its effects

Increasing pupils' knowledge about alcohol and its effects was one of the objectives of the In:tuition programme and consequently was one of the secondary outcomes of the primary school trial. All pupils, regardless of whether they had ever had an alcoholic drink, were asked whether each of the following six statements were true or false, which tested their knowledge of alcohol and its effects on the body:

- 'Alcohol is a drug' (True)
- 'Alcohol affects different parts of the body' (True)
- 'You can buy alcohol in shops and supermarkets from age 16' (False)
- 'A person might have trouble standing or walking if they have drunk alcohol' (True)
- 'If someone drinks often they will get used to it and it won't harm their body' (False)
- 'Alcohol is usually swallowed and travels around the body in the blood' (True).

As shown in Figure 5, most pupils in both groups knew that a person might have trouble standing or walking if they have drunk alcohol (95 per cent of the intervention group and 93 per cent of the control group) and that alcohol affects different parts of the body (93 per cent intervention and 91 per cent control). More than eight out of ten pupils also knew it was *false* that if someone drinks often they will get used to it and it will not harm their body (81 per cent intervention and 82 per cent control). Around two-thirds (64 per cent intervention and 61 per cent control) were correct in answering that you cannot buy alcohol in shops from age 16 (although around a third thought you could). There was least certainty, particularly in the control group, about whether alcohol is a drug (67 per cent of the intervention group compared with 54 per cent of the control group knew it is) and about the fact that alcohol is usually swallowed and travels around the body in the blood (65 per cent intervention and 57 per cent control group pupils answered this correctly). These latter two findings suggest a difference in knowledge of these issues between the intervention and control groups at follow-up. This was explored with more detailed analysis.

Figure 5: Primary school pupils' knowledge of the health effects of alcohol (follow up survey)



To investigate any difference in overall knowledge between the groups, each pupil was awarded a score between zero and six. The mean score at the school level for pupils included in the final model for each group is shown in Table 7, which shows a higher mean score for pupils in the intervention group.

Table 7: Mean scores for knowledge

Outcome	Group	Number of schools	Number of pupils	Mean
Knowledge score at follow up	Control	30	1022	4.37
	Intervention	24	726	4.64

Multilevel modelling was then conducted to compare knowledge between the groups, controlling for any measurable differences between them. The results, shown in Table 6, show that pupils in the intervention group had on average better knowledge about alcohol than those in the control group, with an effect size of 0.17 (see Appendix C for an explanation of effect sizes). This result was, however, not significant at the p=0.05 threshold (as shown in Table 6). The model intervention coefficient was 0.197 which means that the intervention group scored on average nearly 0.2 points higher than the control group on a scale of 0-6 points. Therefore, there is some evidence to suggest that the In:tuition programme improves knowledge about the health effects of alcohol, compared to existing provision.

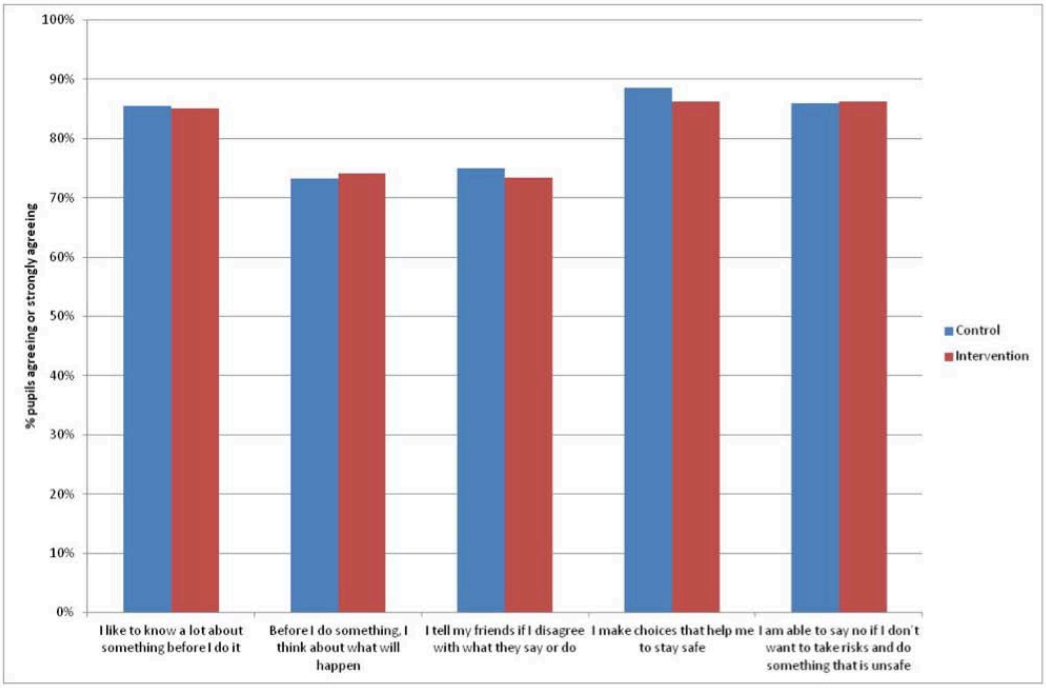
3.2.3 Results for the secondary outcome: decision-making skills

Improving decision-making skills is one of the main aims of the In:tuition programme, and was therefore one of the secondary outcomes of the primary school trial. Responses to the following survey questions were used to explore decision-making:

- I like to know a lot about something before I do it
- before I do something, I think about what will happen
- I tell my friends if I disagree with what they say or do
- I make choices that help me to stay safe
- I am able to say no if I don't want to take risks and do something that is unsafe.

At follow-up, more than eight out of ten pupils in both groups reported that they made choices that help them to stay safe (86 per cent of the intervention group and 89 per cent of the control group) and that they are able to say no if they do not want to take risk and do something unsafe (86 per cent of both groups). Most liked to know a lot about something before making a decision (85 per cent intervention and 86 per cent control). Slightly fewer, yet still around three quarters in both groups, felt able to tell their friends if they disagreed with what they said or did (73 per cent of the intervention group and 75 per cent of control pupils) and reported that they think about what will happen before they do something (74 per cent intervention and 73 per cent control). These findings suggest there was little difference between the self-reported decision-making skills of pupils in both groups at follow-up (see Figure 6).

Figure 6: Primary school pupils' attitudes towards making decisions (follow up survey)



To explore this further, a score was derived from pupils' responses to questions listed above, with a possible range from -10 to 10 (see Appendix B for details). Table 8 shows the average scores for pupils in the intervention and control groups.

Table 8: Mean scores for decision-making skills

Outcome	Group	Number of schools	Number of pupils	Mean
Decision-making skills at follow up	Control	30	1021	5.84
	Intervention	24	727	5.89

Multi-level modelling showed that there was no significant difference between the groups (Table 6) and therefore no evidence that the In:tuition programme has an impact upon how pupils make decisions about staying safe and minimising risk.

3.2.4 Results for the secondary outcome: understanding of social norms relating to the proportion of young people who drink alcohol

Improving pupils' understanding of the social norm that most young people will *not* have had a whole alcoholic drink before they are age 16,[12] is one of the main aims of In:tuition and hence one of the secondary outcomes of the trial. Table 9 shows that the majority of pupils in both groups did not understand this social norm. On average, only 24 per cent of pupils in the intervention group, and 28 per cent in the control group, understood that most young people would not have a whole alcoholic drink before age 16.

Table 9: Mean proportion of pupils answering the social norms question correctly

Outcome	Group	Number of schools	Number of pupils	% giving correct answer
Social norms at follow up	Control	29	996	28
	Intervention	24	712	24

The results from statistical multi-level modelling (see Table 10) show that pupils in the intervention group are no more likely than those in the control group to understand the social norm that most people will not have an alcoholic drink before they are 16. Therefore, there was no evidence to suggest that the In:tuition programme improves pupils' understanding of social norms relating to alcohol consumption of teenagers.

[12] Two-fifths (39 per cent) of young people aged 11-15 have drunk a whole alcoholic drink at least once (Fuller, 2014)

Table 10:Odds ratio for the 'social norms' secondary outcome model (binary outcome variable, logistic regression)

Outcome description	Outcome measure	Odds Ratio	95% confidence interval (lower)	95% confidence interval (upper)	p-value	Number of intervention pupils in model	Number of control pupils in model	Number of intervention schools in model	Number of control schools in model
Secondary	Understanding of social norms	0.83	0.66	1.04	0.12	712	996	24	29

Summary

Overall there is no evidence that the In:tuition programme has an impact on the primary outcome of interest, resistance skills, for primary school pupils. There were no significant effects on the secondary outcomes, and although primary pupils in the intervention group had on average slightly better knowledge about alcohol and its effects than those in the control group, this was not significant either.

4. The Secondary School Trial

Key findings:

- **Primary outcome: frequency of drinking –** there was no evidence that participation in the In:tuition programme had an impact on the proportion of pupils aged 12-13 who were drinking frequently.
- **Secondary outcome: onset of drinking** Although the proportion of pupils that had had an alcoholic drink by the time of the follow up survey was slightly higher in the intervention group than the control group, statistical modeling showed that this difference was not significant. There was no evidence of an impact of the programme on delaying onset of drinking.
- **Secondary outcomes:** There was no significant difference between the intervention and control groups in terms of pupils':
    - knowledge of alcohol and its effects on health
    - resistance skills (or confidence to manage peer pressure)
    - decision making skills
    - understanding of social norms relating to the proportion of young people who drink alcohol (that not all young people under 16 will have had a whole alcoholic drink)
- **Fidelity:** Of the 28 schools randomised into the intervention group, only five were known to have delivered at least some of the intervention lessons (note that of the 28, three schools officially withdrew from the trial and four schools did not participate in the baseline survey or were excluded for incorrect administration).

4.1 Methodology

Trial Design

The trial adopted a cluster-randomised design, whereby secondary schools were recruited to the trial and then randomised either to receive the In:tuition programme or not – thus becoming intervention and control groups respectively (schools were made aware at the time of recruitment that they would be randomised into either group). Control schools continued with their normal PSHE/alcohol education curriculum. Intervention and control groups were equal in size.

The trial was designed as an 'effectiveness' trial; with every attempt to mirror how In:tuition might be delivered for real. Schools were recruited from a large national sample and initially had minimal assistance with intervention delivery. However, due to few schools registering on the In:tuition website, the evaluator agreed in the early stages of the trial to start assisting schools with the registration process. The trial thus became an 'efficacy' trial as the level

of assistance that schools received is unlikely to be matched in a real-world delivery scenario.

Eligibility

Secondary schools in England containing Years 7 and 8, in an agreed sampling frame of local authorities (see below) were eligible for the trial. This included maintained schools, academies, free schools, pupil referral units and independent schools. Special schools and schools which had already registered to use the In:tuition programme were excluded.

Sample Size

In a survey of drinking behaviour in Year 8 within targeted schools, Lynch *et al.* (2012) showed that 11% were drinking once a month or more. To detect a reduction in the prevalence of frequent drinking (once a month or more) from 10% to 7.5% would require the recruitment of 80 secondary schools for randomisation to intervention and control i.e. 40 in each group. This assumes a power of 0.80 and an achieved sample of 50 pupils (two classes) per school. From the results of models of drinking frequency containing baseline data, we did not anticipate an appreciable design effect but the study was adequately powered to detect a prevalence change from 10% to 7% with roh=0.01 and 10% to 6.5% with roh=0.02.

Sampling and recruitment

For the secondary trial the aim was to recruit 80 schools with 50 pupils i.e. two classes per school.

Schools were randomly selected from an original sampling frame of 33 local authorities (LAs) agreed with ICE Creates (the programme developers). Authorities were selected in geographical clusters in order to retain other areas for future evaluation of In:tuition. Schools were excluded if they were already registered with ICE Creates. As nearly all secondary schools within the sampling frame were being drawn in the sample, stratification was unnecessary. The initial recruitment strategy was the same as for primary schools - to draw large samples of schools, predicting that recruitment might be difficult (our experience is that research projects relating to life-skills and health-related subjects are often given less of a priority in schools than those relating to other 'core' subjects, such as mathematics, English or science).

As anticipated, recruitment of secondary schools was particularly difficult, possibly because they have less curriculum flexibility than primary schools. To achieve this response, it was necessary to draw two top-up samples of LAs and schools, in addition the original sample. These consisted of 14 and 8 LAs respectively. This was despite reminder strategies, which included sending

letters with information about the trial and the intervention, as well as sending faxes, emails and a telephone reminding campaign.

The final complete sampling frame of LAs is presented on a map in Appendix F.

During the sign-up process, schools were asked to declare which three or four classes[13] they wished to nominate for the intervention. This nomination occurred before randomisation to ensure that schools could not choose classes on the basis of which group (intervention or control) they had been allocated. Schools were trusted to stick to these nominations so they are not a complete guarantee that class choice did not change after randomisation.

We sought feedback from schools which did not wish to participate, but despite contacting schools on numerous occasions did not always receive a response. A total of 106 secondary schools gave feedback (see Table 11 below).

Table 11: Reasons for non-participation in the secondary school trial

Reason	N Schools
Non-specific; unable to help	78
Too short notice (*see below)	9
Lack of time	6
Involved in other projects	3
Did not feel programme content was appropriate	4
Timetable concerns	3
Too few students	2
School closing	1
Total = 106	

Due to difficulties with recruitment the baseline survey period was extended from the summer term 2013 into September 2013. These circumstances meant that the questionnaires were completed by schools at different times during a survey period that included June-July 2013 and September 2013[14].

Randomisation

The randomisation process was identical to that adopted for the primary school trial, as outlined in Section 3.1 (except block sizes for secondary schools were 38, 6, 5, 5 and 1).

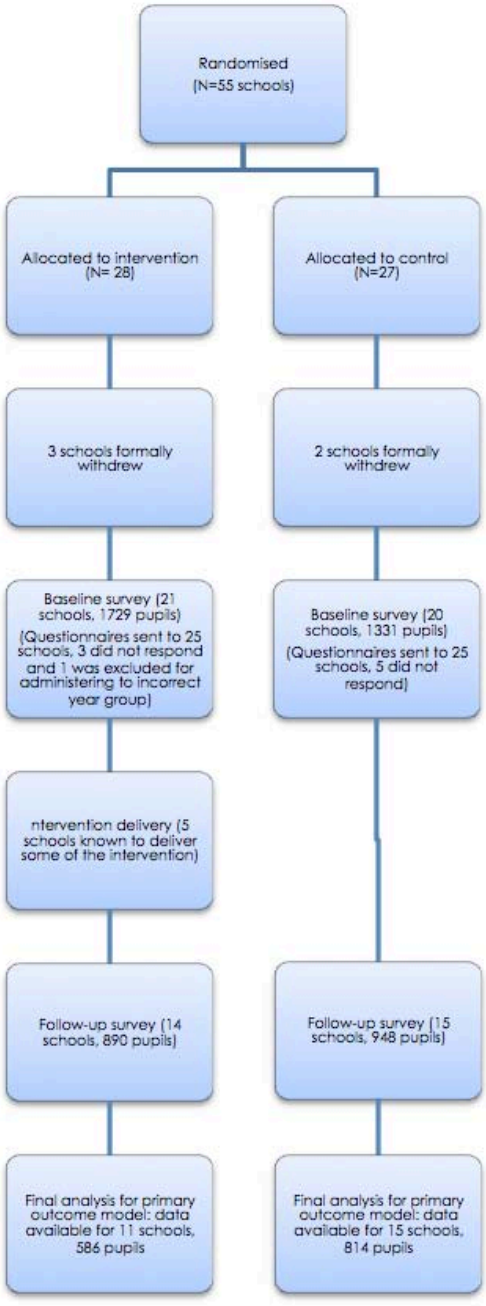
13 In order to ensure 50 pupils per school were retained at follow-up.
14 A flag was added to the final analysis to indicate the timing difference in the administration of the baseline survey, which could have an impact on outcomes.

4.2 Results for the Secondary School Trial

4.2.1 Participants

As shown in Figure 7, a total of 55 schools were recruited and randomised into 28 intervention schools and 27 control schools. The total number of secondary schools invited to take part to recruit 55 schools for the trial was 1513 across 55 LAs.

Figure 7: Secondary school trial



4.2.2 Attrition and exclusions

As shown in Figure 7, following randomisation, three intervention and two control schools withdrew prior to the baseline survey, leaving 25 in each group (including 25 in the intervention group expected to register to deliver the In:tuition programme). A total of 21 intervention schools and 20 control schools then completed baseline surveys, yielding data from 1729 intervention pupils and 1331 control pupils (a total of 3060) in Year 7 (age 11-12).

4.2.3 Participants in the end-point survey sample

A total of 50 schools were included in the sample for the follow up survey – these included all schools which were recruited at baseline and sent questionnaires (regardless of whether they completed them) and excluded the five schools which actively withdrew from the trial. The number of schools completing both baseline and follow-up surveys was 12 intervention schools and 15 control schools. The number of pupils completing both surveys was 757 intervention and 933 control pupils. This is larger than the number included in the primary outcome analysis as the latter required pupils to have a full complement of data from the relevant variables. Table 12 below shows the characteristics of the secondary *schools* in the primary outcome analysis compared with the population of LAs from which schools were drawn. There were no significant differences between the final analysed sample and the population for region and percentage FSM. This suggests that within the final sample we have a spread of schools that reflects the population from which they were drawn, at least in terms of these two variables.

Table 12: Secondary school profile at follow up survey

		Population		In sample	
		Number	%	**Number**	**%**
Government Office Region	North East	179	16	9	35
	North West/Merseyside	126	11	1	4
	Yorkshire & The Humber	108	10	4	15
	West Midlands	131	12	3	12
	South East	391	35	6	23
	South West	183	16	3	12
Total N=		1118		26	
% students eligible for FSM 2010/11 (5 pt scale)	Lowest 20%	123	15	2	9
	2nd lowest 20%	215	26	4	17
	Middle 20%	234	29	6	26
	2nd highest 20%	163	20	9	39
	Highest 20%	83	10	2	9
Total N=		**818**		**23**	

Table 13 shows the baseline characteristics of pupils for whom data was collected at baseline *and* follow up. A school-level comparison between the intervention and control group means identifies any imbalance between the groups in terms of the measured baseline characteristics. There were two significant differences found between the pupils in the control and intervention groups. Pupils in the control group were more likely than intervention pupils to be an older sibling, and those in the intervention group were more likely than control pupils to describe themselves as belonging to a religious group other than Christian. None of the other comparisons revealed statistically significant differences, which suggests that the final intervention and control groups of secondary school pupils can be regarded as broadly equivalent.

Table 13: Baseline characteristics of secondary school pupils

Covariate	Group	Number of Schools	Number of Pupils	Mean	P-value
Frequency of drinking at baseline	Control	15	814	0.0518	
	Intervention	11	586	0.0616	0.591
Surveyed after July	Control	15	814	0	
	Intervention	11	586	0.0909	0.251
Age at test in months	Control	15	811	147.8046	
	Intervention	11	586	147.8529	0.86
Self reported free school meals	Control	15	814	0.2411	
	Intervention	11	586	0.2145	0.563
Boys	Control	15	812	0.4813	
	Intervention	11	582	0.4859	0.921
Ethnicity non white	Control	15	814	0.2112	
	Intervention	11	586	0.1104	0.219
Ethnicity unknown	Control	15	814	0.0388	
	Intervention	11	586	0.0414	0.859
Eldest child*	Control	15	792	0.4053	0.034 *
	Intervention	11	570	0.3276	
Number of siblings	Control	15	794	2.1763	
	Intervention	11	579	2.1916	0.925
Comprehensive to sixteen	Control	15	814	0.2667	
	Intervention	11	586	0.2727	0.974
Comprehensive to eighteen	Control	15	814	0.2667	
	Intervention	11	586	0.0909	0.279
Grammar school	Control	15	814	0.1333	
	Intervention	11	586	0	0.223
Rural school	Control	14	747	0.0714	
	Intervention	10	518	0.1	0.813
How often does anyone you live with drink alcohol inside your home? (Q26)	Control	15	765	0.6377	
	Intervention	11	545	0.7249	0.166

Covariate	Group	Number of Schools	Number of Pupils	Mean	P-value
Number of different ethnic categories (school)	Control	13	715	12.5385	
	Intervention	9	438	13.1111	0.684
Attitude towards school (composite variable from Q7)	Control	15	814	28.496	
	Intervention	11	586	28.0935	0.279
Christian	Control	15	814	0.0983	
	Intervention	11	586	0.1379	0.305
Other religion*	Control	15	814	0.0324	0.046 *
	Intervention	11	586	0.1981	
Religion unknown	Control	15	814	0.019	
	Intervention	11	586	0.0134	0.491
Have you ever been drunk?	Control	15	814	0.0774	
	Intervention	11	586	0.0816	0.854
Age when first drank an alcoholic drink (Q15)[15]	Control	15	814	12.9299	
	Intervention	11	586	12.7441	0.399
Have you ever drank alcohol without a responsible adult present? (Q16A)	Control	15	813	0.0662	0.165

Secondary schools from which data was collected at baseline *and* follow-up[16] were grouped into one of four categories depending on the extent to which they were known to have completed the In:tuition programme. As shown in Table 14 below, only five of these secondary schools delivered at least some of the lessons.

Table 14: Fidelity of secondary intervention schools to the In:tuition programme

	Number of secondary schools	
	Completed baseline only	Completed baseline and follow up
All or most lessons completed	2	2
6 or fewer lessons completed	3	3
Known to have completed no lessons (e.g. withdrew)	13	5
Known to have registered on the In:tuition website but number of lessons completed unknown	3	1
Total	21	11

[15] In order to boost the number of cases that could go into the models, anyone who said that they had never drank alcohol by the time of the follow up survey were assigned an age of first drink greater than or equal to 14.

[16] And therefore had pupils eligible for the completers (ITT) analysis

Due to initial low registration rates on the In:tuition website, the following assistance was offered by the evaluator to intervention schools: the sending of an introductory guidebook, assistance with registration via telephone conversations and directing school staff to the ICE Creates helpline. Furthermore, ICE Creates was occasionally prompted to respond to helpline calls. As for the primary school trial, it is not possible to say to what extent this external help altered fidelity but it meant that the trial represented a slightly exaggerated picture of how well schools might deliver the programme in reality.

Information on *why* schools did not go on to register or deliver the lessons was limited, but indicates that challenges relating to staff shortages and/or limited time available on the timetable were the main factors.

The issues of attrition and programme fidelity outlined above are likely to have an impact on the measurable effects of the intervention; these issues were particularly prevalent for the secondary school trial.

4.2.4 Results for primary outcome: Frequency of drinking

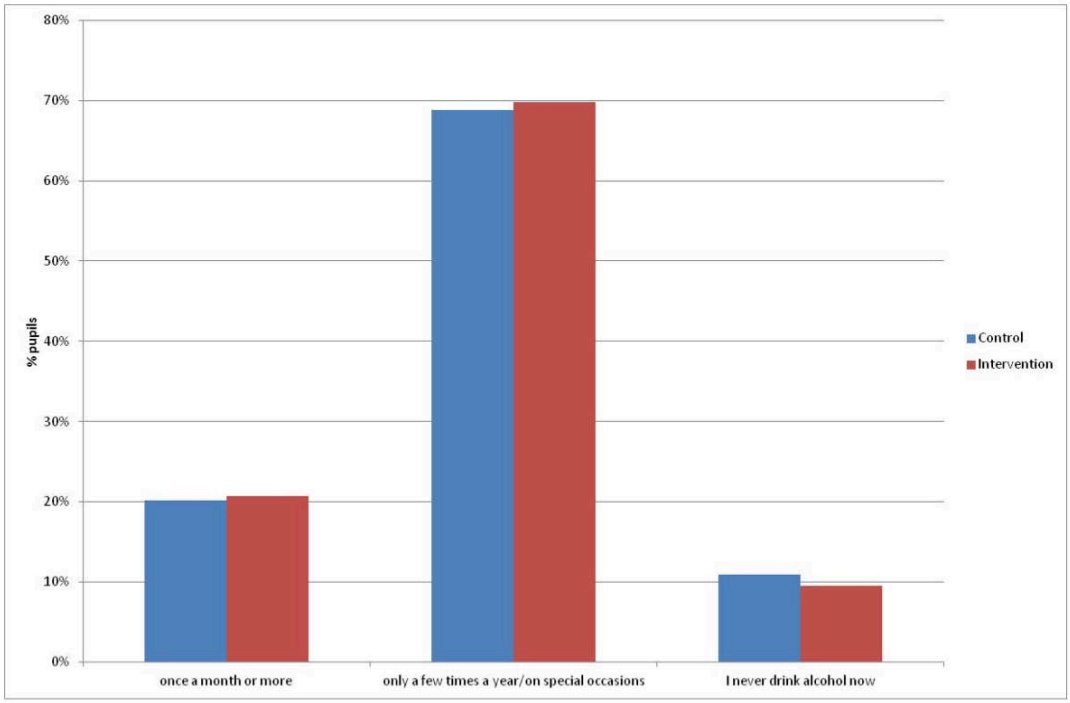
One of the main aims of the In:tuition programme in secondary schools is to reduce the frequency of drinking among teenagers. Consequently, this was agreed as the primary outcome of the trial in secondary schools. The analysis of frequent drinking was based on pupils who drank alcohol *once a month or more* (see Appendix B for an explanation of how the measure was constructed).

Table 15 below shows that, on average, around one in ten pupils in the intervention and control schools were frequent drinkers at the time of the final survey. Looking at the proportion of frequent drinkers *out of those who had ever had a drink* (Figure 8), one in five reported drinking once a month or more (21 per cent of intervention group pupils and 20 per cent of control group pupils); around one in ten said that they did not drink alcohol any more (10 per cent of intervention group and 11 per cent of control group pupils). Most pupils only drank alcohol a few times a year, for example on special occasions (70 per cent of the intervention pupils who had ever had a drink; 69 per cent control).

Table 15: Percentage of frequent drinkers at follow-up (out of all pupils eligible for the model)

Outcome	Group	Number of schools	Number of pupils	% of pupils at follow-up
Frequency of drinking regularly at follow up	Control	15	814	9
	Intervention	11	586	11

Figure 8: Frequency of drinking alcohol among secondary school pupils who had ever had a whole alcoholic drink by the time of the follow up survey (n=652)



Multilevel modelling was then carried out to control for measurable differences between the intervention and control pupils to explore if there was any difference in the proportion who drank frequently at follow-up. The main analysis was an intention-to-treat (ITT) analysis (see Section 2.3.1). The results of the modelling (see Table 16) show that there was no significant difference between the groups and therefore no evidence that participation in the In:tuition programme had an impact on the proportion of pupils aged 12-13 who were drinking frequently.

Table 16 Odds ratio for the 'frequency of drinking' (primary outcome) and 'onset of drinking' (secondary outcome) models (binary variable, logistic regression)

Outcome description	Outcome measure	Odds ratio	95% confidence interval (lower)	95% confidence interval (upper)	p-value	Number of intervention pupils in model	Number of control pupils in model	Number of intervention schools in model	Number of control schools in model
Primary	Frequency of Drinking	0.87	0.51	1.47	0.599	586	814	11	15
Secondary	Onset of Drinking	0.96	0.64	1.43	0.841	605	835	11	15

To explore this finding further, the characteristics of pupils in the two groups at follow-up were explored to investigate if they can still be regarded as equivalent, at least in terms of measures we have. There was some evidence of imbalance between analysed groups in baseline characteristics (see Section 4.2.3 above). This probably resulted since attrition between baseline and follow-up was so extensive. The proportion of pupils who were the eldest sibling was significantly higher in the control than the intervention groups (41 per cent and 33 per cent respectively) and the proportion who were of a non-Christian religion was significantly higher in the intervention group as compared to control (20 per cent and three per cent respectively). Note that neither of these variables was significant in the primary outcome model so their imbalance *per se* is not a problem, however they may be indicative of wider imbalance that we could not measure. Due to the large attrition between baseline and follow-up, multiple imputation of missing data was not possible with the secondary school dataset.

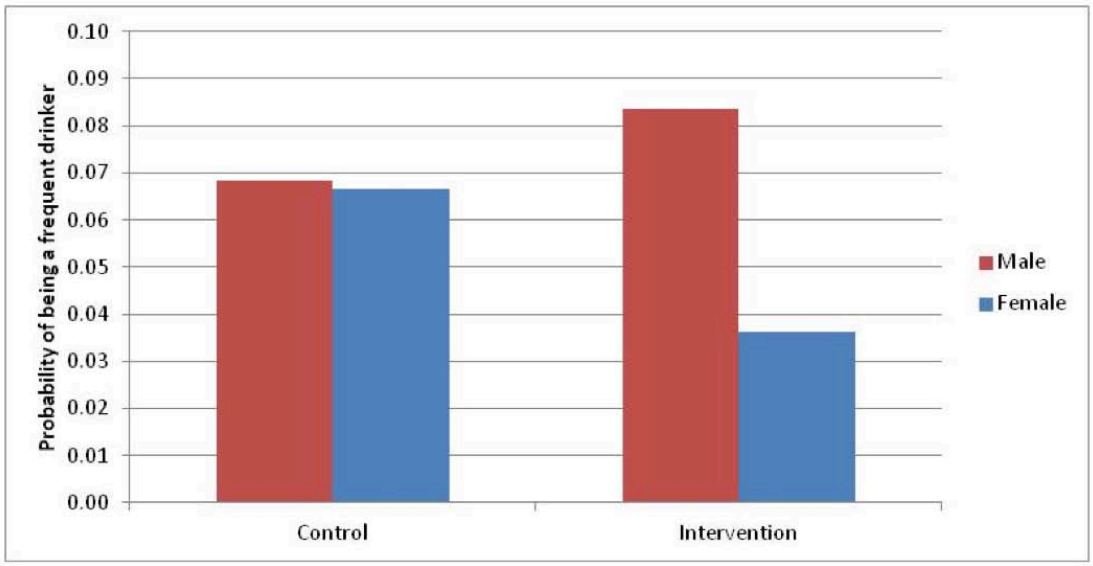
To assess any differential impact on frequency of drinking by pupil characteristics, sub-group analysis was carried out on the ITT dataset including: gender; ethnicity; free school meals (self-reported); age in months; whether a pupil has siblings/is the eldest sibling; religious group; parental drinking in the home and attitudes to school (a composite measure) using interaction terms. As summarised above, the ITT analysis showed that overall, the In:tuition programme had no significant effect on frequency of drinking. However, a statistically significant finding emerged relating to the interaction between the intervention and gender (see Table 17). This suggests that the intervention worked differentially for males and females to the extent that males were more likely and females were less likely to be frequent drinkers compared to their counterparts in the control group at follow-up (Figure 9). However, as explained in Section 2.3.8, this analysis is exploratory and would require further research to attribute a genuine effect of the intervention. No other significant effects of the programme on sub-groups were found.

Secondary school primary outcome (frequency of drinking) gender sub-group analysis

Variable name	Fixed Effect	Standard Error	Degree of Freedom	value	p-value
Intercept	.117	.514	1363	.228	.820
Intervention	-.640	.368	22	-1.738	.096
Frequency of drinking at baseline	1.849	.262	1363	7.050	.000
Comprehensive school to age 18	-1.222	.456	22	-2.682	.014
Grammar school	-1.470	.622	22	-2.363	.027
Have you ever been drunk?	1.134	.253	1363	4.481	.000
Age of first alcoholic drink	-.214	.035	1363	-6.174	.000
Male	.029	.258	1363	.114	.910
Male in the intervention group	.855	.383	1363	2.234	.026*

**statistically significant interaction*

Figure 9: Probabilities of being a frequent drinker: the interaction between the intervention and gender for frequent drinking



ITT analysis does not consider the extent to which the intervention is followed, so additional 'on-treatment' analysis was carried out to examine whether the intervention had a different effect in schools that had completed the In:tuition programme than schools that did not. As described in Chapter 5, **adherence to the programme**, or 'fidelity', varied considerably between schools. The on-treatment analysis comprised of a logistic regression with the fidelity information added as covariates (see Appendix F for the output). There was no significant difference between the groups, therefore there is no evidence to show that teaching more of the In:tuition programme has an impact on frequency of drinking in pupils. This means that although it was hypothesised that the extent to which the In:tuition programme is delivered matters in terms of reducing the frequency with which pupils drink alcohol, there is no evidence to support this theory.

Further 'on-treatment' analysis was carried out to look at whether In:tuition had an impact on frequency of drinking if pupils **received the specific lessons on this topic** (lessons two and three, 'Alcohol, the body and the law') (see Appendix F for the output). Lessons two and three were only known[17] to have been taught in five of the secondary schools. There was no significant difference between the frequency of drinking of pupils that had received lessons two and three, and those that had not. Note that due to the small number of schools involved in this comparison, it is likely that it was underpowered i.e. unable to detect a genuine difference should it exist.

[17] Lesson data was not available for all schools

4.2.5 Results for secondary outcome: onset of drinking

Pupils were asked 'have you ever had an alcoholic drink – a whole drink, more than just a sip/taste?' which required a binary ('yes/no') response.

Multilevel modelling analysis explored the impact of the In:tuition lessons on delaying the onset of drinking – are pupils in the intervention group less likely to have started to drink by the follow up survey?

To add context to the modelling, it should be noted that the proportion of pupils that had had at least one whole alcoholic drink[18] by the time of the follow up survey (when most pupils were age 12-13) was slightly larger in the intervention group (56 per cent) than the control group (48 per cent) (Table 18). Furthermore, Figure 10 shows how the drinking behaviour of pupils who had *not* had an alcoholic drink at baseline varies at follow up. Almost three in ten intervention group pupils (29 per cent) who had not drunk at baseline had had at least one whole drink of alcohol by the time of the follow up survey, compared to just under a quarter of the control group (23 per cent).

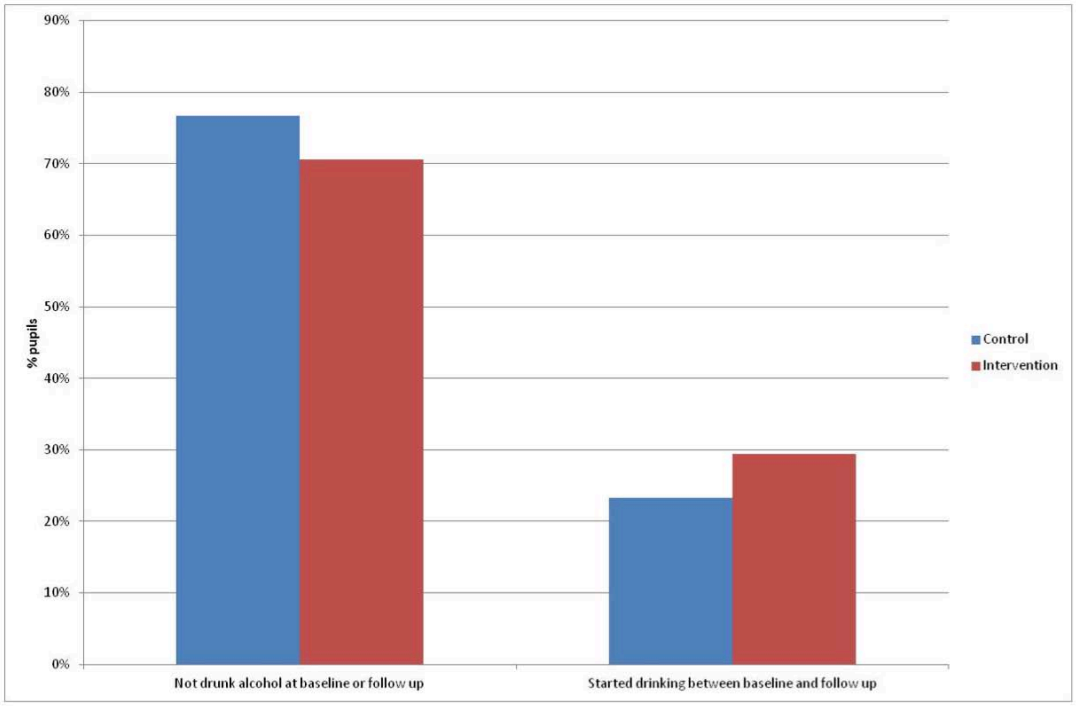
Table 18: Proportion of secondary school pupils that had had an alcoholic drink by the time of the follow up survey[19]

Outcome	Group	Number of schools	Number of pupils	% pupils
Drinking at follow up	Control	15	835	48
	Intervention	11	605	56

[18] Including those who had already had an alcoholic drink at baseline

[19] The data reported in this section is based on analysed data only (i.e. the cases that went into the final primary outcome model) for consistency with the rest of the chapter.

Figure 10: Drinking behaviour at follow up of the secondary school pupils who had *not* had an alcoholic drink at the time of the baseline survey[20]



Out of the group of pupils who had already had an alcoholic drink by the time of the follow up survey, the mean age at which they did this was similar across the two groups: an average age of 10.8 years in the control group and an average of 10.5 in the intervention group.

The results of the multilevel logistic regression (Table 16) revealed that pupils who had received the In:tuition lessons were no more or less likely to ever have had an alcoholic drink than those in the control group and, therefore, there is no evidence that the In:tuition programme influences the onset of drinking among 12-13 year olds.

4.2.6 Context: drinking behaviour in 12-13 year olds

In addition to onset and frequency of drinking (described in Sections 4.2.4 and 4.2.5 above), secondary school pupils were asked further questions about their drinking behaviour[21]. Note that the results in this section have not been tested for statistical significance because they were not specified as primary or secondary outcomes.

As shown in Table 19, over half of pupils that had drunk a whole alcoholic drink said they had never been drunk. However, three in ten pupils that had

[20] Based on analysed data only, i.e. the cases that went into the final primary outcome model
[21] The results reported in this section are based on the whole sample at follow up, and not just the cases eligible for the models.

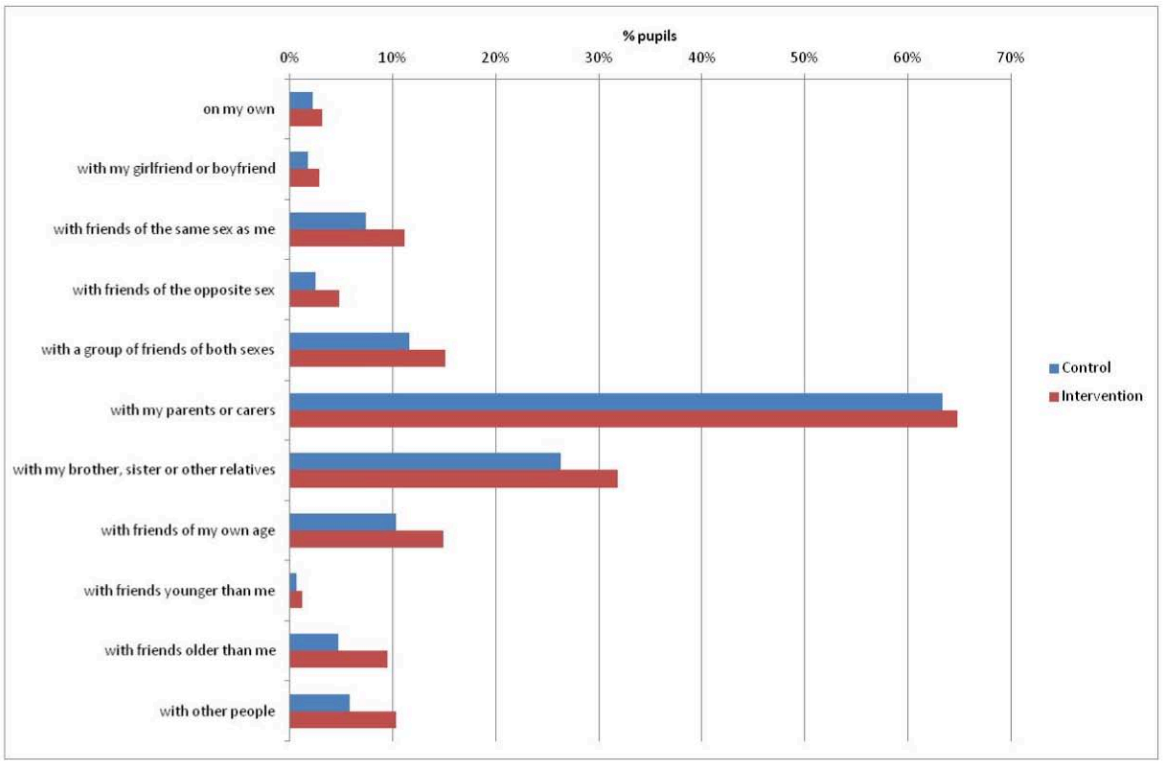
drunk alcohol in the intervention group reported that they had been drunk at least once (30 per cent), compared to a quarter in the control group (25 per cent). A higher proportion of intervention group pupils said they had drunk five or more alcoholic drinks on one occasion than control group pupils (30 per cent and 22 per cent respectively, N=753). Furthermore, almost half of drinkers in the intervention group said they had consumed alcohol without a responsible adult present, compared to a third of drinkers in the control group (48 per cent and 33 per cent respectively, N=838). Overall, this paints a picture where pupils in the intervention group drink more heavily than those in the control group, and are more likely to be unsupervised, but it must be emphasised that these differences have not been tested for significance, and it is possible that some of these activities may have taken place prior to participating in the In:tuition programme.

Table 19: The number of times pupils who said they had drunk a whole alcoholic drink reported having ever been drunk

	Control	Intervention
Never	53%	51%
Once	15%	15%
2-5 times	7%	11%
6-10 times	2%	3%
More than ten times	1%	1%
I don't know	23%	19%
Total	100%	100%
N=	390	440

Pupils tended to drink in the company of family, with over six in ten of both groups reporting that they drink with parents/carers, and around three in ten drinking with their siblings or other relatives (see Figure 11). Around one in ten said they drank alcohol with friends of their own age. Very few reported drinking on their own (three per cent (15 people) in the intervention group, two per cent (10 people) in the control group).

Figure 11: Who do secondary school pupils drink with? (follow up survey; all who ever had a drink)



The vast majority of pupils that drank alcohol said they did so for special occasions such as birthdays or Christmas (86 per cent in the intervention group and 85 per cent in the control group). The next most common reason was because they like the taste of alcohol (49 per cent in the intervention group and 42 per cent in the control group). Very few pupils said that they drank because they felt pressured to drink by their friends (five per cent of the intervention group and three per cent of the control group).

Pupils who had never had a drink of alcohol

At the point of the follow up survey, 861 pupils said they had not had a whole drink of alcohol. Around one in ten of these pupils thought that they *would* have had a whole drink before they turned 16 (11 per cent in the intervention group and eight per cent in the control group) while about a third were unsure (35 per cent and 31 per cent in the intervention and control groups respectively).

The most common reasons given for not ever having drunk alcohol were:

- it is bad for your health (intervention 56 per cent, control 62 per cent)
- I don't feel it is right to drink at my age (intervention 52 per cent, control 41 per cent)
- I have learned about the negative aspects about alcohol (intervention 36 per cent, control 35 per cent)
- it is against the law to buy alcohol if you're under 18 (intervention 36 per cent, control 30 per cent)
- religious reasons (intervention 15 per cent, control 28 per cent).

4.2.7 Secondary outcome: Knowledge of the health effects of alcohol

As part of the aim of the In:tuition programme on improving drinking behaviour, the lessons include content intending to improve pupils' knowledge of the effects of alcohol, and therefore this formed one of the secondary outcomes of the secondary trial. All pupils, regardless of whether they had ever had an alcoholic drink, were asked six 'true or false' questions which tested their knowledge of alcohol and its effects on the body:

- 'Police can take alcohol from under 18s drinking in a public place' (True)
- 'You can buy alcohol in shops and supermarkets from age 16' (False)
- 'Alcohol is usually swallowed and travels round the body in the blood' (True)
- 'If you drink alcohol on an empty stomach the effects are stronger' (True)
- 'Someone over 18 can buy alcohol for me as long as I don't buy it myself ' (False)
- 'If you stop drinking and switch to soft drinks or coffee then it will speed up the rate at which alcohol leaves the body' (False).

Most pupils knew that the police can take alcohol from under 18s in a public place (85 per cent in both the intervention and control groups). Almost three quarters of pupils were correct that you cannot buy alcohol from age 16 (71 per cent of the intervention group and 69 per cent of the control). Around six out of ten pupils knew that if you drink on an empty stomach the effects are stronger (66 per cent of intervention pupils and 60 per cent of control group pupils) and that alcohol usually swallowed and travels round the body in the blood (64 per cent of intervention pupils and 65 per cent of control pupils). However, there were particular gaps in knowledge in relation to the other questions. The majority of pupils were wrong in thinking that if you switch to soft drinks or coffee it speeds up the rate at which alcohol leaves the body

(85 per cent intervention pupils and 83 per cent control group pupils answered this incorrectly) and more than half thought someone over 18 could purchase them alcohol from a shop (61 per cent of the intervention group and 58 per cent of the control group answered this incorrectly).

A knowledge score was calculated for each pupil based on their answers to the questions listed above (also see Appendix B). Out of a possible score of six, the mean knowledge score was just over three in both the intervention and control groups (see Table 20).

Table 20: Mean knowledge scores at the follow up survey

Outcome	Group	Number of schools	Number of pupils	Mean
Knowledge score at follow up	Control	15	829	3.36
	Intervention	11	594	3.37

Mean scores out of a possible range of 0 to 6

The results from statistical modelling also showed that there was no statistically significant effect of the In:tuition programme on knowledge of alcohol and its effects (Table 21).

Table 21: Effect sizes for 'knowledge', 'resistance skills', 'decision making skills' and 'social norms' (secondary outcomes) models (continuous variables, multilevel models)

Outcome description	Outcome measure	Effect size	95% confidence interval (lower)	95% confidence interval (upper)	p-value	Number of intervention pupils in model	Number of control pupils in model	Number of intervention schools in model	Number of control schools in model
Secondary	Knowledge of the Effects of Alcohol	0.02	0.14	-0.09	0.691	594	829	11	15
Secondary	Resistance Skills	0.01	0.09	-0.08	0.885	671	924	11	15
Secondary	Decision Making Skills	-0.06	0.03	-0.15	0.188	754	923	12	15
Secondary	Social Norms	0.05	0.18	-0.07	0.399	691	846	12	15

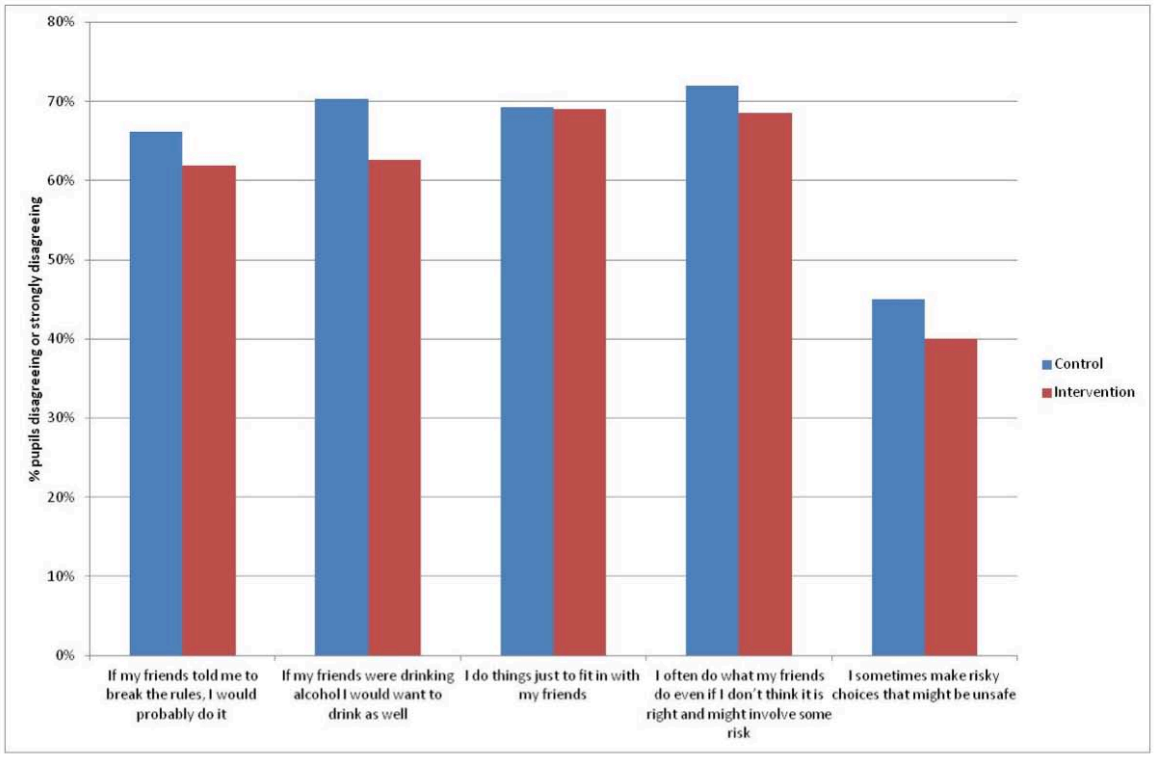
4.2.7 Secondary outcome: Resistance skills (confidence to manage peer pressure)

Resistance skills, or giving pupils the confidence to manage peer pressure was integral to the life skills approach of In:tuition, so this formed another of the secondary outcomes. In order to measure resistance skills, a score was derived from pupils' responses to the following questions:

- if my friends were drinking alcohol I would want to drink as well
- if my friends told me to break the rules, I would probably do it
- I do things just to fit in with my friends
- I often do what my friends do even if I don't think it is right and might involve some risk
- I sometimes make risky choices that might be unsafe.

Between six and seven out of ten pupils in both groups *disagreed* with most of the statements above (suggesting they make independent decisions and can manage peer pressure), although fewer than half disagreed with the final statement (see Figure 12). Nearly a third (32 per cent) of the intervention group and 29 per cent of the control group agreed that they sometimes made risky and unsafe choices.

Figure 12: Proportion of secondary pupils that disagreed to some extent with the resistance skills statements (follow up survey)



A score was derived from pupils' responses, out of a possible range of -10 to 10, with 10 representing the highest level of resistance skills. The control group had a mean score of 4.03 compared to the intervention group mean of 3.42 (Table 22). However, the results from statistical modelling show that there was no statistically significant effect of receiving the In:tuition lessons on resistance skills (Table 21).

Table 22: Mean score for resistance skills

Outcome	Group	Number of schools	Number of pupils	Mean
Resistance skills at follow up	Control	15	924	4.03
	Intervention	11	671	3.42

Mean scores out of a possible range of -10 to 10, with 10 representing the strongest resistance skills

4.2.8 Secondary outcome: Decision-making skills

As part of the life-skills approach, the In:tuition programme aims to build pupils' decision making. This formed one of the secondary outcomes of the secondary school trial, based on the following questions:

- I think about what might happen to me before I do something
- I think about what might happen to other people before I do something
- I like to understand all the facts before making a decision about something
- When I make a decision, I often think about the effects it might have.

Self-reported decision making skills were very similar across the two groups of interest, for example three-quarters of the intervention and control groups said that they think about what might happen to other people before they do something (74 per cent and 75 per cent respectively). A similar proportion thought about what might happen to them (73 per cent of the control group and 71 per cent of the intervention group). Furthermore around two thirds of secondary pupils said that they like to understand all the facts before making a decision (66 per cent of the control group and 64 per cent of the intervention group agreed or strongly agreed with this statement), and that they often think about the effects it might have when they make a decision (69 per cent of the control group and 66 per cent of the intervention group agreed or strongly agreed with this statement).

As decision making was one of the secondary outcomes of the trial, a score was derived from pupils' responses to the questions listed above (also see Appendix B). The control group had a similar mean decision-making score to the intervention group (see Table 23).

Table 23: Mean decision making scores of secondary school pupils

Outcome	Group	Number of schools	Number of pupils	Mean
Decision-making skills at follow up	Control	15	923	3.48
	Intervention	12	754	3.27

Mean scores out of a possible range of -8 to 8, with 8 representing the strongest decision making skills

The multilevel modelling confirmed that there was no evidence of impact of the In:tuition lessons on decision-making; there was no statistically significant difference in average scores between the groups (see Table 21).

4.2.9 Secondary outcome: Understanding of social norms relating to the proportion of young people who drink alcohol

In addition to giving pupils facts and information about alcohol and its effects, In:tuition also aimed to improve pupils' understanding of social norms relating to the proportion of young people engaging in drinking behaviours. The survey asked secondary school pupils whether the following questions were true or false:

- 'Most young people aged 11-15 have never drunk a whole alcoholic drink' (True)
- 'Most people aged 15-16 get drunk regularly' (False).

The evidence shows a lack of understanding of social norms relating to alcohol. At least eight out of ten pupils answered both questions *incorrectly*. Only a fifth (20 per cent of the intervention group and 18 per cent of the control group) knew that most young people aged 11-15 will not have had a whole alcoholic drink, and fewer (17 per cent and 16 per cent) were correct in thinking that most 15-16 year olds do not get drunk regularly.

A score was derived from pupils' responses to the two 'true or false' questions, and multi-level modelling was carried out on this measure. Pupils in the intervention and control groups appeared to have similar levels of understanding of social norms; on average the intervention group scored 0.37 out of 2 compared to the average control group score of 0.34 (see Table 24).

Table 24: Mean score for understanding of social norms

Outcome	Group	Number of schools	Number of pupils	Mean
Social norms at follow up	Control	15	846	0.34
	Intervention	12	691	0.37

Mean score out of a possible range of 0 to 2

The multi-level modelling showed that there was no statistically significant difference in the average scores of pupils in the two groups; there was no evidence that the In:tuition programme improved pupils' understanding of social norms relating to alcohol consumption of teenagers (see Table 21 above).

Summary

Overall there is no evidence that the In:tuition programme has an impact on the primary outcome of interest, frequency of drinking of secondary school pupils, and there were no significant effects on the secondary outcomes either. This indicates that the In:tuition programme is not meeting its stated aims.

5. The Process Evaluation

Key findings

- Overall, case-study teachers reported a range of *perceived* impacts of In:tuition on pupils relating to the aims of the programme and the outcomes of interest of the trial, including increased knowledge and awareness, development of strategies and skills and modified behaviour. However, most felt that they would have achieved the same impact using existing PSHE provision.
- Teachers were positive about the content and teaching approaches, but adapted the programme to take into account the time available, the needs/context of the school, content covered in other lessons and pupils of different abilities in their class.
- Suggestions for improvements included:
  - reducing the duration and content of the programme
  - providing different formats to deliver the resources such as slides and more visual resources
  - greater differentiation of content for pupils with lower levels of literacy
  - pupils would like more opportunities for discussion and more pupil led activities.

The main purpose of the process evaluation was to examine:

- fidelity (whether the programme was delivered as intended)
- how the programme was implemented
- parental engagement and use of hometasks
- effective elements in programme delivery
- views on programme content
- challenges and barriers to delivering a successful programme
- suggestions for improvements.

These factors are likely to be central to whether the programme has a statistical effect on the outcomes of interest explored above. As noted in Chapters 3 and 4, there is no evidence of any statistical effects of the programme on the outcomes measured. The process evaluation findings could help to explain why this is the case, and help to understand elements of the programme which have been successful or a particular challenge.

5.1 The Process Evaluation Methodology

This section is based on findings from the case-study visits to schools carried out in June and July 2014. All intervention schools recruited to the trial which then went on to register on the In:tuition website, were invited to take part in the more-in-depth qualitative investigation. The aim was to achieve five primary schools and five secondary schools with varying background contexts. In reality, given difficulties faced with general recruitment to the trial, schools included were those willing to take part (and thus are likely to be those most engaged with the programme). This, and the fact that only small numbers of schools and individuals were included in this qualitative element of the trial (see Table 25), means that the results are *illustrative* and should not be generalised.

Table 25: Case-study participants

	Number of schools	Number of staff	Number of pupils
Primary schools	6	6	46
Secondary schools	3	6	24
Total	9	12	70

The findings from the case-study visits supplemented those from a teacher survey, to which small numbers of teachers responded (22 teachers across 19 primary schools and eight teachers across five secondary schools).

5.2. Results

5.2.1 Programme fidelity

Fidelity: were 12 lessons delivered?

Of the 22 primary school teachers who responded to the teacher survey, only three delivered the entire programme of 12 lessons, while 18 did not (one did not respond). Of the eight secondary school teachers, only two delivered the entire programme[22]. Tables 26 and 27 illustrate which lessons were delivered by teachers who responded to the survey.

[22] This information informed the on-treatment analysis described in Chapters 3 and 4.

Table 26: Lessons delivered in primary schools (teacher survey)

Table 26 Lessons delivered in primary schools (teacher survey)				
Lesson	**Number who delivered lesson**	**Of those, number who felt 40 minutes was about right**	**If delivered, number rating lesson very good/good*** **	**If delivered, number rating lesson very poor/poor* **
Lesson 1: How shall we start	15	12	10	1
Lesson 2: This is me	17	15	13	-
Lesson 3: This is me	15	11	11	1
Lesson 4: Say it like it is	13	11	10	-
Lesson 5: Say it like it is	12	12	8	2
Lesson 6: Social norms	14	7*	9	-
Lesson 7: What should I do?	10	8	6	1
Lesson 8: Alcohol and the body	11	5**	8	-
Lesson 9: Seeing is believing	7	3	7	-
Lesson 10: Seeing is believing	5	2	4	-
Lesson 11: Looking to the future	4	3	3	-
Lesson 12: Looking back, looking forward	4	3	2	-

Total N=22

**Five felt 40 minutes was too short, **Four felt 40 minutes was too short*

****Those who delivered the lessons did not always rate how much they liked them*

Table 27 Lessons delivered in secondary schools (teacher survey)

Table 27 Lessons delivered in secondary schools (teacher survey)				
Lesson	**Number who delivered lesson**	**Of those, number who felt 40 minutes was about right**	**If delivered, number rating lesson very good/good**	**If delivered, number rating lesson very poor/poor**
Lesson 1: How will it start?	6	5	6	-
Lesson 2: Alcohol, the body and the law	7	6	6	-
Lesson 3: Alcohol, the body and the law	6	6	6	-
Lesson 4: Social norms	7	5	6	-
Lesson 5: Say it like it is	5	5	5	-
Lesson 6: Say it like it is	4	4	3	-
Lesson 7: Standing up, standing out	3	3	3	-
Lesson 8: Standing up, standing out	3	3	4	-
Lesson 9: Being assertive	6	4	6	-
Lesson 10: I get by with a little help from my friends	3	2	2	-
Lesson 11:Looking to the future	2	1	2	-
Lesson 12: Looking back, looking forward	2	1	2	-

Total N= 8

Across case-study schools, at the time of the visits in June and July 2014 only two primary and two secondary schools had completed the programme in its entirety. Several schools (at the time of interview) hoped to complete additional sessions prior to the end of term. Of those that had not completed the programme, several reported having started the programme and then having run out of time or reported that allocated sessions had subsequently been used for other priorities.

Twelve of the 22 primary teachers who responded to the survey felt that the overall length of 12 lessons each for 40 minutes was 'about right'; three said 'too long' and two said 'too short' (the remaining five did not respond). Of the eight secondary school teachers who responded, four said the programme length was 'about right', while three others who responded said 'too long'. The tables above indicate that the majority of teachers did not complete the entire programme (numbers delivering lessons reduced towards the end of the programme). The main reason for not completing the programme was lack of curriculum time (13 primary teachers and four secondary teachers).

Fidelity: were lessons delivered sequentially?

Tables 26 and 27 (based on data from the teacher surveys) show that lessons were not always delivered sequentially; some teachers taught lessons later in the programme after not delivering some of the earlier lessons. Therefore, shows teachers were selective about which lessons they taught. There was also case-study evidence of variability in the extent to which schools delivered In:tuition as a sequential, structured series of 40-minute lessons. About half of the case-study schools adapted their delivery approach to suit the needs and circumstances of the school. The main reason for this deviation related to the overall length of the programme:

> *It was too long for us to manage with the rest of the curriculum we need to follow in school* (primary)
> [We] *had to cut it down to get it into the 6 weeks time frame available – Jan-Feb half term* (secondary)

Fidelity: were 40 minutes allocated to each lesson?

In case-study schools, there was variability in the length of time devoted to individual lessons. In about half of the schools, the recommended 40 minutes per lesson had been timetabled. Staff in these schools reported that some lessons took longer than others, but there was sufficient flexibility to accommodate this. In the other schools, including two of the secondary schools, timetables meant that around 30 minutes was available for In:tuition. Comments included:

> *I spent 30 minutes on each session – the same amount of time as would normally be given over to a circle time session* – [we] *crammed it in a bit* (primary).
> *Because of the school timetable and structure we only have a 30 minute session available. But* [staff] *have adapted the content accordingly* (secondary).

Tables 26 and 27 show that teachers who responded to the surveys did not always think 40 minutes for each individual lesson was 'about right'. Some were considered too short, while the case-study evidence suggests variations in views about whether schools are able to allocate this amount of time to such lessons.

Fidelity: were lesson plans used as intended?

There was evidence that most teachers adapted the content of lessons to suit their needs. In case-study schools, the majority of interviewees noted adapting the lesson plans to some extent, generally by cutting out some content, largely necessitated by time constraints and the amount of material to be covered. In other cases, lesson plans were modified to take into account content already delivered in other lessons; to focus on particular needs/issues relevant to the school; and to tailor aspects of session delivery to the needs/preferences of the class. Comments included:

> *This was a challenge, there was a lot to fit in the lessons. We didn't have the full 40 minutes as there was only 25 minutes of pastoral time available.* So *that's one of the main reasons why I have adapted the lessons and made it more verbal – saves a lot of time by not getting them to work through the worksheets and write it down* (secondary).

> *I generally followed the plans but often just did verbal feedback sessions rather than following the activities and homework tasks specified in the programme* (primary).

The majority of interviewees commented on the amount of information the lesson plans contained, and whilst recognising their quality and comprehensive nature, many suggested they were '*too wordy*' and teachers were faced with '*information overload*' prompting them to modify the lesson plans in order to facilitate session delivery:

> *I had what the objectives were, and had the resources, but maybe didn't do it exactly as it was there, because I don't want to be constantly reading the sheets, so you use some of your professional judgement as well, and deliver it in a way that is flowing* (primary).

Findings from the teacher survey revealed that five of the 22 primary teachers and four of the eight secondary teachers felt the lessons were too detailed (and therefore might have adapted them).

Survey findings also suggested that some teachers did not feel the lessons were appropriate for all pupils and, therefore, may have adapted them. For example, six teachers in primary schools and three in secondary schools did not think they were suitable for all abilities. Eight in primary schools did not think they were appropriate for different religions.

If teachers surveyed were to use the programme again, 14 of the 22 in primary schools and six of the eight teachers in secondary schools would like to select bits of it and adapt it.

5.2.2 Programme implementation

Most teachers who responded to the survey (15 of the 22 in primary schools and seven of the eight in secondary schools) taught the lessons individually over a period of days/weeks, rather than as an intensive block of lessons grouped together. In secondary schools, lessons were most often taught in tutorial time or as part of the Personal, Social and Health Education (PSHE) curriculum.

In case-study schools, the three primary and one secondary school that had delivered the programme in its intended format generally ran In:tuition sessions on a weekly basis, either replacing previous PSHE lessons or as part of timetabled pastoral sessions. The other case study schools generally implemented a block delivery approach in response to timetable constraints and the primary schools also largely opted to deliver the programme in the summer term after SATs had been completed (note we asked primary schools to deliver the programme in Year 6). As a teacher in a primary school said:

> *Delivering in a block is often the only way we can do these education pieces.*

5.2.3 Parental engagement and use of hometasks

Only six of the 22 primary teachers who responded to the teacher survey, and four of the eight surveyed in secondary schools, introduced the programme to parents. If they did, it was most often by letter/in writing, although two primary schools held a meeting for parents dedicated to the programme.

In case-study schools, introductory meetings had not been held in any of the schools for the following reasons:

- **No perceived need to introduce In:tuition to parents**: Interviewees suggested that parents trusted the school to deliver high-quality, appropriate PHSE-type material, so it was not necessary specifically introduce In:tuition which was just seen as another area of curriculum to be delivered.
- **Difficulties in engaging parents in school-life.** Both secondary and primary school staff noted difficulties in engaging parents with the school and that securing attendance at meetings was often problematic. Several staff spoke of their reluctance to overburden parents with requests to come into school and preferred to reserve these requests for 'more important meetings' (primary).
- **Sensitivity around In:tuition subject matter.** In several schools (primary and secondary), staff noted their reservations about raising the profile of the In:tuition programme content amongst parents.
- **Logistics and timing**. Several primary school interviewees noted that meetings were not held as there had not been sufficient time to organise a meeting prior to implementing the programme or that staff were not yet sufficiently confident in the delivery of the programme, so would be unable to respond to parents' questions. Across the case-study schools, interviewees reported very little feedback from parents prior to, or during, the programme's delivery.

None of the 22 primary school teachers surveyed sent home *all* of the homework tasks and only seven sent home *some* of the homework tasks. Among the eight secondary school teachers, none sent home all hometasks; three sent home some. Six primary school teachers had received negative feedback from parents (the survey did not gather details).

Amongst case-study schools there was variability in the extent to which homework tasks were used with interviewees in around half of the six primary schools and two of the three secondary schools noting that homework had *not* been given. In one secondary school, this was because In:tuition was delivered in scheduled guidance/support sessions for which homework was not ever given. In the other secondary school, individual staff members delivering the programme had opted not to give out the homework tasks. Primary school staff noted that they had not set homework tasks largely as a result of school-based issues – such as the homework timetable having already been established prior to the onset of In:tuition and the existing levels of homework from other curriculum areas. Primary school staff contended that they aimed to encourage parents to focus more on supporting children with numeracy and literacy, so did not want anything to interfere with this - '*it muddied the waters if we then tried to add in PSHE*'.

Several pupils who had not completed hometasks noted that they would have been interested in doing them alongside their parents:

> *It would have been quite interesting to do it – to do the quiz with my parents to find out how much they knew – test what they know about it* (secondary school pupil).

Where homework was given, interviewees noted that it was kept 'fairly low key' to try and encourage pupils and their parents to engage, and the tasks relating to alcohol was most commonly distributed:

> *With all the pressure on literacy and numeracy, I didn't push this quite as much and made it a bit more informal for the pupils so didn't push the homework aspect* (primary)

Primary staff reported that some parents had engaged with the tasks and some completed worksheets had been returned. Pupils were said to have enjoyed the tasks, but as a result of time constraints, and low levels of returns, homework was not generally integrated into lessons, other than some low-level discussion and verbal follow up. A secondary school interviewee noted that the alcohol-related task had been particularly well received by pupils who enjoyed working through the sheet with their parents. In this case, the task was used as a discussion point in subsequent lessons and the staff member suggested that they would like to expand this element of the programme in the future:

> *They* [pupils] *liked the fact that parents had homework. They were very talkative about what their parents had done, how they and scored. It proved to be a big talking point* (secondary).
>
> *At first, mine were quite surprised about the questions that they asked, but just went along with it. It made them realise just how things have changed and how different society is from then to now and how many more people are smoking and drinking at a young age now* (secondary pupil).

5.2.4 Effective elements in programme delivery

In case-study schools, primary and secondary school staff highlighted a range of factors that facilitated the effective delivery of the In:tuition programme. There were no differences evident between the phases.

Effective lesson plans

The vast majority of interviewees noted that the lesson plans were instrumental in the successful delivery of the programme, although as noted previously, these had often been subject to alteration (largely to accommodate time constraints). Lesson plans gave structure to the lesson; clearly highlighted the learning objectives; provided comprehensive background information; and set out the necessary activities to be completed. In one secondary school, this was seen as particularly beneficial to the large number of non-teaching staff delivering In:tuition:

> *It was especially good for non-teaching staff .... As a teacher, you can navigate through a lesson – but we have a lot of non-teaching staff and the lessons plans were especially helpful in explaining to them what they needed to do* (secondary).

Where adaptations had been made, they generally involved the introduction of extension activities and examples to reflect the school and locality contexts and needs of particular pupil cohorts.

Effective resources and activities

Most interviewees in case-study schools valued the resources available to support the delivery of In:tuition, commenting on their quality, appropriateness and effectiveness in facilitating pupils' engagement in the sessions. The more visual and interactive resources were particularly valued. However, several interviewees had modified and adapted resources and the way they were used. This was particularly so in relation to worksheets which were not always considered an appropriate or effective means of delivery. As a result, the worksheet topics were taken and delivered in ways compatible with the school's normal approach in which pupils had a greater level of involvement and creativity.

Both primary and secondary staff valued the pupil-centred interactive and dynamic nature of some programme activities whereby pupils spent a lot of the session 'doing' something and the teachers acted more as facilitators.

Alongside this, enhanced collective learning was facilitated through the division of the class into small groups which encouraged the active participation of all (or most) class members in discussions. Most interviewees identified the role play sessions and scenarios as being a particular strength of the programme. The following quotations illustrate staff and pupils' thoughts on how In:tuition activities facilitated the programme's successful delivery:

> *Mixing the children out of their normal friendship groups – splitting up all the confident ones who usually sit with each other. Having mixed ability groups helped encourage wider participation of more children* (primary).

They love role play - they'd do it all day if they could. They get really into it. We used the worksheets to help and guide them, but they didn't really fill them all in because they were busy doing the more interactive tasks – they learn better that way (secondary).

Pupils' perspectives generally echoed those of their teachers in that they also identified the interactive and participatory elements as being a highpoint of the programme. Both primary and secondary pupils highlighted the 'fun' and interesting nature of the sessions and also acknowledged that this was a highly-effective means of learning. The following illustrate some pupils' views on the delivery of In:tuition:

I find it [role play/scenarios] *easier to stay in my brain than when I'm just listening, It's a bit more active so you can remember it better* (primary pupil).

It was best when we all talked together and discussed things, then did it in small groups, then did a role play or a poster or something (primary pupil).

Among teachers who responded to the survey, 15 of the 22 primary teachers and five of the eight secondary teachers reported that pupils engaged positively with the activities.

5.2.5 Views on programme content

The fidelity information above (Tables 26 and 27) shows that teachers who did not deliver the entire programme were selective about which lessons they taught, which was likely to be based on which they felt were most relevant to the needs of their class. For instance, lessons on alcohol, the body and the law, on social norms, and on being assertive were most popular with the secondary school teachers who responded to the survey.

In the majority of case-study schools, the In:tuition programme content was well received by staff and pupils in both primary and secondary phases, with interviewees generally agreeing that lessons (and associated resources) were age-appropriate; of high quality; and relevant to pupils' lives; '*it felt like they were learning something about life*' (primary). Pupils' interest in, and engagement with, the individual lessons, were seen as key to the programme's success.

Whilst most lessons were valued, several were identified by staff as being of particular benefit because of the interplay of their substantive content and the activities involved. For example:

The 'say it like it is' session. That was a real strength of the programme – especially where there were mini tasks, not just whole class discussions. This gave less confident students the chance to participate (primary).

In addition, the effectiveness of individual sessions related to perceived needs and local characteristics and contexts. In the case of the secondary schools, it was suggested that the alcohol and social norms sessions were especially important. Comments included:

It's a very deprived area, and alcohol is of prime importance. They all wanted to know more about alcohol (secondary).

Social norms was important because our students do not get that from their parents. Understanding how to behave in certain situations is not something that they get from parents because the parents don't know how to behave properly (secondary).

We focussed the programme on the culture of the environment that we're in. The society that they're in and we've adapted the In:tuition resources to meet our needs and what our children see on a daily basis (secondary).

Several primary school teachers noted that the content was especially useful as a transition tool to help prepare pupils for their move to secondary school. This point was also made by several pupils: – '*we are moving onto secondary school…and it is good to do this sort of thing now*' (primary pupil).

As well as generally enjoying the sessions, pupils suggested that the content was relevant and useful to them, now and in the future, equipping them with knowledge, awareness and strategies to deal with a range of issues and situations. The following comments give a flavour of how and why pupils valued the content of particular themes, topics and lessons. Note that although the content is different for primary and secondary programmes, the lesson titles and themes overlap.

- **Alcohol and the body/law**

  It gives you the information for the future, so you know not to use alcohol or drugs (primary pupil).
  It helps us for the future, so that we don't over-drink because it shows us the consequences (secondary pupil).

- **What should I do/social norms/being assertive**

  It's preparing us for the future….it's probably the sort of thing that we are going to have to face, like bullying and stuff, and people taking drugs' (primary pupil).
  It was good when they gave us the scenarios and we had to say what we would do or not do in those situations. They were really good because they helped you understand about how other people feel about situations (secondary pupil).

- **This is me**

  You had to say what you liked about yourself. It was quite nice because it made you feel a bit happier about yourself (primary pupil).

- **Say it like it is**

  I liked doing the one where you had to break bad news to people (primary pupil).

- **Seeing is believing**

  I liked the one where you had to design a drink and come up with a slogan and a logo. It was good because we had to work as a team, all have a different role… It was good to work as a group, then each one had to show it to the rest of the class then we all discussed it. We got a lot out of that one (primary pupil).

- **Looking to the future**

  The ones where we had to come up with our own character and say what they wanted to achieve when they were older. That was good because you could say what the challenges were that they might face (secondary pupil).

  It gave me a little example of what I could do when I'm older (primary pupil).

5.2.6 Challenges and issues encountered in delivering the programme

Alongside the positive response to the programme content summarised above, staff and pupils identified some challenges in relation to the delivery of the In:tuition programme and some elements of its content.

The main challenge for teachers was reading – and remembering – the level of detail in the lesson plans. Amongst those who responded to the survey, ten of the 22 primary school teachers and four of the eight in secondary schools agreed that the programme required more preparation time than anticipated. Similarly, staff in case-study schools referred to the amount of detail contained in the lesson plans and the associated preparation time required for them to remember the content and lesson objective. For one primary school teacher, the key challenge revolved around; *'getting your head round what it was asking you to do, and what it was asking the pupils to do'.* Another commented that: *'despite reading it the night before and at the dinner time of the day, I found it very difficult to remember all the notes so I could stand up and deliver it'.*

Some pupils commented that some sessions contained too much content and verbal information, and on occasion, there could be an over-reliance on completing worksheets:

> *Sometimes it switched us off a bit when* [teacher] *was talking a lot. There was these sheets to read off and it dragged on sometimes – we thought it would never end* (primary pupil).
>
> *I think it was a lot to take on over 12 weeks. There was a lot of information in each lesson, so you remember some stuff, but some stuff you don't remember* (primary pupil).

Among teachers who responded to the survey, only a minority reported facing technological challenges, such as access to computers (four primary teachers and one secondary teacher) or difficulties logging on to the programme website (three primary teachers and one secondary teacher).

However, 15 of the 22 primary teachers and six of the eight secondary teachers wanted to be able to look at the entire programme as a whole (rather than having to access lessons one by one on the website). Some teachers wanted paper materials (ten primary teachers and six in secondary schools), despite most agreeing that it was easy to navigate the site. Moreover, nine primary teachers and four secondary teachers wanted materials available in different formats (such as slides, or to make them accessible on mobile technology).

Similar issues were raised by individual interviewees from the case-study schools, with a minority of teachers noting that they had faced some initial difficulties in accessing the programme on-line and that log-on details and passwords had to be shared between staff and pupils (in order to complete the questionnaires). One primary school teacher commented that '*navigating the on-line resources was difficult* whilst another thought that it was a shame that, because he had completed and signed off the programme, he was unable to access it online anymore.

Suggestions for improvements

Most of the improvements highlighted by staff in case-study schools focussed on addressing the difficulties they had experienced in delivering the programme. As such, the main suggestions included:

- reducing the overall duration of the programme to fit into half-term schemes of work
- condensing the information contained in the lesson plans to enhance clarity
- making the lesson plans available in different formats, such as slides
- reducing the use of worksheets and written element of the programme to save time and encourage greater pupil participation:

  If it's written, they are more suspicious that it might be held against them in the future – they are more happy to talk about it (secondary)
- increasing the use of visual resources and interactive activities:

  There are a lot of fantastic scenarios – maybe enhance these by adding videos to illustrate/demonstrate them (secondary)
- having greater differentiation of session content to increase the participation of students with lower levels of literacy.

Although teachers generally liked the programme, as described above, the extent of the changes they suggest here provide a further indication of why many of them adapted the programme and its resources before delivering the content to pupils.

Pupils were generally happy with the programme's content and the way it was delivered with many interviewees not being able to suggest any specific improvements. However, the following suggestions for improving In:tuition were made by a minority of pupils:

- address the balance between teacher-led activities and pupil activity within sessions, including reducing the written component of some lessons:

Some of the worksheets were quite boring – where you just filled them in without doing any activity (primary pupil).

- provide greater opportunities for discussion to consolidate the learning from individual and group research activities.
- increase IT and visual element of the programme: *Could maybe have more videos and more things off the internet.*
- provide opportunities for pupils to be more involved in planning the lesson activities - *I would like us to be more involved...to make suggestions about what we could do, like make it into a play or something* (primary pupil).
- modify the content of some of the sessions – some primary pupils did not engage with the session on future careers because it was not seen as relevant to them at this stage. Both primary and secondary pupils suggested that having opportunities to explore some session content in more detail would be useful, especially in relation to peer pressure and alcohol.

  You could maybe have a bit more time talking about why people have chosen to use substances like drugs and drink – not just why it is bad for you (secondary pupil).
- introduce additional topic areas, including on-line safety and how to deal with abuse.

5.2.7 The Impact of In:tuition

Staff and pupils in case-study schools were asked for their *perceptions* on the extent to which In:tuition had impacted on the school, parents and pupils. These views should be considered in the context of the quantitative evidence described in Chapters 3 and 4 which found no significant evidence of impact of In:tuition in primary or secondary schools.

Overall, most case-study teachers felt that they would have achieved the same impact using existing provision, however one secondary school felt that because the programme was supplied by an external company it meant that the pupils were more receptive to the content than internally developed resources. Another secondary school said that using In:tuition meant they had covered topics such as assertive behaviour earlier than they would have done otherwise. One primary school felt that using the In:tuition programme had helped the school put more emphasis on transition to secondary school.

Impact on schools

The main benefit identified by both primary and secondary school staff focussed on the availability of a set of high-quality resources that would save teachers significant amounts of lesson preparation time in the future.

> *But seeing the resources, it was absolutely great – not having to think of something to have to do for 6 weeks was great. There was something there that I could manipulate and use to suit my purpose* (secondary).

It's definitely saved time, to have the materials all there for you, and you can print out what you want to use (primary).

This seems to contradict the finding above that some teachers felt the lesson plans were too detailed and required unanticipated preparation time. This could mean views varied across interviewees, or that on one hand teachers benefited from the resource being readily available yet on the other hand still felt they required preparation time in using/adapting them (but perhaps less time than having to develop their own).

In addition, it was felt that some staff, especially non-specialists could feel 'out of their comfort zone' in delivering PHSE type curriculum, so had benefitted in terms of their CPD through involvement in the programme and access to In:tuition's resources, and structured lesson plans.

Impact on parents

None of the interviewees noted any impact on parents arising from the delivery of the In:tuition programme. This could be because they did not fully engage parents in the programme and/or did not seek their feedback.

Impact on pupils

Although no significant effects of the programme were evident from the quantitative analysis (Chapters 3 and 4), a range of *perceived* impacts arising from involvement in In:tuition were identified by staff and pupils in case-study schools (discussed below). However, some staff questioned the extent to which developments were attributable *solely* to In:tuition, and in some cases (especially in the primary phase) it was still too early to be able to quantify how the lessons learned will translate into positive change in pupils' behaviours or experience. Many of the perceived impacts were thought to involve slight and subtle - but nevertheless important - changes in pupils' attitudes and behaviour, which in many cases, involved preparing them for the future, rather than altering their present circumstances.

Staff (especially in the secondary schools) noted that a lot of pupils lacked exposure to positive behaviour and culture outside of the school environment, so in this respect, In:tuition was perceived to have had a very positive impact on their wider development and growth by showing them that there are 'other ways' of acting, feeling and behaving. Staff did believe, however, that the pupils had become more aware of how they should behave, and why they should behave in that way, and also more equipped to handle themselves and difficult situations in a more appropriate and effective way.

The range of impacts on pupils identified broadly fell into three main categories: increased knowledge and awareness; development of strategies and skills; and modified behaviour, all of which relate to the outcomes of interest examined by the trials in Chapters 3 and 4.

Increased knowledge and awareness

Primary and secondary school pupils noted that through various sessions, they had learned new facts and increased their knowledge, especially in relation to health and wellbeing, most notably involving alcohol, cigarettes and other drugs. Pupils claimed to have developed more sophisticated understandings of the effects of alcohol, and its wider social implications:

> *It made us understand more about how bad it can get - what too much drinking and smoking can do to you. Smoking and drinking can affect your future – like if you put it on social media, other people can see what you do and it might put them off giving you a job* (secondary pupil).
>
> *It's made me more aware of the dangers of drugs and alcohol and how it can really affect your life and take over your life completely. It cannot just damage your body, but can damage everything else like relationships and can drag you into bankruptcy* (secondary pupil).
>
> *I've learned that if you drink too much, people can take advantage of you and you're in danger* (secondary pupil).

Staff and pupils also noted that the programme had enhanced their perceptions around alcohol in a number of ways, including raising their awareness that not all young people drink alcohol and that controlled drinking, in the right contexts (relating to age and social situation), was not necessarily a bad thing. In short, the sessions were said to have helped them develop a balanced view of alcohol consumption, and in general, most pupils contended that drinking and smoking was not a significant issue amongst their peers - it was generally not seen as a 'cool' thing to do:

> *I know now that if it's a special occasion, like Christmas or New Year, it's OK to have a couple of drinks of alcohol. But smoking is still really dangerous* (secondary pupil).
> *I know that my brother drinks too much, gets drunk every night and needs to sort his life out* (secondary pupil).

These comments relate to the secondary outcome about improved knowledge of alcohol and its effects in both the primary and secondary trials. Although staff and pupils reported here that knowledge had improved, which was also a finding of a review of the evidence base (Martin *et al.*, 2013), the statistical modelling showed that knowledge of pupils in the intervention group did not differ significantly from that of pupils in the control group, indicating that existing provision would have had the same effect. However, the analysis carried out on the knowledge outcomes was ITT, and as such did not take into account the extent to which a school had delivered In:tuition. We know that the schools involved in the case studies had completed at least part of the In:tuition programme, and so these comments provide an indication that where In:tuition had been taught, knowledge was perceived to have improved. Perhaps if fidelity had been better within the intervention group this could have translated into a discernible effect.

Development of strategies and skills

Interviewees noted that In:tuition had been effective in enhancing pupils' ability to cope with numerous potential social and emotional situations and challenges, with peer pressure being the prime focus. This was apparent for both primary and secondary pupils. The scenarios were seen to have been of particular use in helping pupils understand various situations and give them (collective) experience and insights into how they could respond in the future. Pupils were said to have become more empowered to make the right decisions, based on increased awareness and understanding combined with knowledge of appropriate methods and techniques. In general, pupils were more able than staff to highlight examples of how the programme had delivered positive examples, but several staff did contend that pupils had become more resilient and better able to make the right decisions. This was especially apparent in relation to primary pupils' impending transition to secondary school for which several teachers suggested that pupils were now they are well equipped to make the right decisions and keep themselves safe:

> *Their awareness has definitely been raised – as a whole class, they all know about peer pressure and how to avoid it, but also how not to put others in a position where they might be pressurising others. The whole class and year group has benefitted in this way* (primary).

The following quotations illustrate some of the ways in which pupils felt that In:tuition had helped them in terms of identifying and managing risk situations:

> *In the past, we might not have thought about these things, but now we've done these scenarios, we now know how to react in these situations in the future – and what we could do to help others do in those situations* (secondary pupil).
>
> *It told me that it's O.k. to do what you want to do, not just to do what everybody else is doing and to make my own decisions* (secondary pupil).
>
> *I know now that if someone asks you to do something that you don't want to do, then they're not really your friend* (primary pupil).

Alongside enhanced decision making, In:tuition was also seen to have facilitated the development of a range of other skills and social and emotional capacity amongst pupils. Teachers suggested that one of the key areas of personal development entailed improvements in the levels of confidence and participation exhibited by their pupils, underpinned by the interactive, collaborative nature of the programme:

> *It's impacted positively on how they've conducted themselves in lessons, they work better in groups, they're more confident in expressing themselves. They can see more clearly what's right and what's wrong* (secondary).

Some pupils noted enhanced communication skills as a result of the programme – for themselves and others – resulting from the mechanics of the programme delivery as well as its substantive content. For example, the mixing of the most confident pupils with the more reserved class members was seen to have increased understanding and empathy as well as enhancing communication skills:

We're [four pupils] *very confident and we all speak all the time. Some others were more shy so we encouraged us to help them. The teachers put us confident ones in groups with the shy people to encourage them and get them to open up a bit more I think it worked because they opened up more and got a bit more confident* (primary pupil).

Pupils and staff concurred that pupils were now better able to have difficult conversations with people and be assertive but not aggressive in their communications with others. There was a general agreement that the communication skills – telling people bad news was a well remembered lesson that will help them in their transition to secondary school.

One lesson we all enjoyed was about someone being in a sticky situation or an embarrassing situation, and you had to work out how to tell them something in a nice way (primary pupil).

Modified behaviour

Given their perceived increase in knowledge and awareness around alcohol, many pupils claimed that their attitudes, and projected future drinking behaviour, had changed as a result of In:tuition, although this did not translate into a quantifiable impact within the secondary school trial (Chapter 4). Pupils suggested very strongly that they would not smoke or take illegal drugs in the future, and their alcohol consumption would be controlled as they had more information on which to make their choices

I won't drink in the future. Not too much (secondary pupil).

We saw a film about moderation – you don't have to drink too much to have a good time. You can like just drink water as well as drinking alcohol all the time (secondary pupil).

Like when you go to a party, someone might bring drink. You're more aware of it and can choose to drink it or not (secondary pupil).

Like at sleepovers – there might be some drink there. But that's up to different people what they choose to do. You don't have to do it if you don't want to (secondary pupil).

5.2.8 Costs of programme delivery

Staff in five of the case-study schools said that teaching In:tuition meant that the school had incurred additional costs, over and above what they would have spent (two schools said no additional costs, two did not comment). The costs mentioned by schools were either related to teacher time (four teachers) or printing (five teachers), although they were not able to quantify the amount of time or expense incurred. As highlighted in Section 4.2.5 on challenges above, additional preparation time was an issue in some schools, with one of the case study primary school teachers commenting *'I should have put [even] more in. I didn't realise how much time I would have to put in to deliver it to the children'.*

The teachers that reported additional costs relating to printing felt that they needed to print a lot of the materials, although they said that where possible they tried to restrict the amount of printing and photocopying. One secondary school teacher said they were able to run the programme on screen, and therefore did not incur any printing costs. Responses from the teacher questionnaire indicated that this was perhaps less of a problem, with only five of the 22 primary school teachers and three of the eight secondary school teachers agreeing that the programme required unanticipated costs.

5.2.9 Future plans for delivery of programme

Of the 22 primary teachers who responded to the survey, just over half (12) said they were not sure if they would continue with the programme in the future, while six said they would and two said they would not (those remaining did not respond). Among the eight secondary school teachers, two were planning to continue with the programme, while one was not and three were not sure (two did not respond).

In case-study schools, the majority of staff noted that they *would* like to deliver In:tuition again in the next year. The key reasons for this focussed on:

- the availability of free, quality resources reduces teacher workload
- pupils' interest and engagement in the programme
- the considered value of the programme as transition tool (for primary schools)
- the relevance of topic areas (and compatibility with other PHSE content).

However, these positive comments were accompanied by assertions that schools may want to make particular changes to the programme to customise it to suit the need and circumstances of their school. Likewise, suggestions for modification and adaptations included:

- reducing the overall length of the programme and selecting the lessons most appropriate for particular pupil cohorts
- using the materials as a starting point and adapting them as appropriate: '*dipping in is the best option*.'

Summary

The process evaluation found that while teachers and pupils were positive about the programme, schools had adapted the programme prior to delivery and a number of areas for improvement were suggested. Although the anecdotal evidence gathered through the interviews indicated that the programme had an impact in the areas of interest of the trial (particularly knowledge, resistance skills and drinking behaviour), this must be considered in the context of the quantitative analysis described in Chapters 3 and 4 which showed that there was no significant difference between pupils that had participated in the intervention and those in the control group. This difference could be related to the poor fidelity to the programme within the intervention group overall, as case study schools, all of which had delivered at least some of In:tuition, reported some perceived impact.

Alternatively, it could also be that pupils in control schools experienced similar improvements as a result of their existing PSHE provision. Such improvements were not captured as part of the process evaluation.

6. Conclusions

6.1 Limitations of the evaluation

One threat to the internal validity of the trial came from the level of measurement attrition, particularly in secondary schools. Although it might be expected for attrition to be greater among control schools, it was in fact greater among intervention schools for both trials. Genuine programme effects on attrition could have led to the comparisons between the intervention and control groups being non-significant. This might have occurred through biased drop-out or loss of power masking a genuine effect of the programme on outcome measures. This possibility was initially investigated through the comparison of baseline characteristics for analysed groups (see Sections 3.2.3 and 4.2.3) and then through multiple imputation of the primary outcome model for the primary school trial (Section 3.2.1). Insufficient data was available to undertake multiple imputation for the secondary trial. For the primary school trial, there was no evidence of imbalance in baseline characteristics for analysed groups and the non-significant effect remained so after multiple imputation.

Potential bias in the findings for the secondary trial could have resulted from two significant differences in the baseline characteristics of pupils for whom data was collected at baseline *and* follow up. Pupils in the control group were more likely than intervention pupils to be an older sibling, and those in the intervention group were more likely than control pupils to describe themselves as belonging to a religious group other than Christian. Although schools (and therefore pupils) were randomised into groups, this difference is likely to have resulted from attrition. Note that both these variables were included in the primary outcome model and neither was significant so their imbalance *per se* is not a problem. However, they may be indicative of wider imbalance that could not be measured.

Another limitation was the nature of the data obtained to conduct analysis on programme fidelity. Information was obtained from a number of sources in order to build a picture of the extent to which schools had delivered In:tuition as intended. One source was output from the In:tuition website where *some* users logged that they had delivered lessons, although data might not be complete as this was not a requirement (i.e. some could have delivered lessons but not logged that they had done so). This data was supplemented by data from the teacher questionnaire, but not all teachers responded. Therefore, on-treatment analysis, which took into consideration the number of lessons delivered and whether the most relevant lesson to the primary outcome had been delivered, was not necessarily complete. The data collected suggested that only 15 of the 34 primary intervention schools and five of the 21 secondary intervention schools delivered some of the intervention. This could explain why there were no statistically significant differences in outcomes between the intervention and control groups in both trials. However, on-treatment analysis was carried out to explore the impact of the level of fidelity on the primary outcomes and results remained the same. Note that the review of literature undertaken by Martin *et al*. (2013) highlighted that difficulty in judging impact of school-based alcohol misuse prevention programmes was partly due to issues related to gauging programme fidelity.

Feedback on why some schools (despite agreeing to participate) did not register for the In:tuition site, or go on to deliver lessons after registering, was limited. One possible reason could have been the delay in availability of programme materials until the September of the autumn term. Materials were initially scheduled for availability in July 2013; this was communicated to schools in their initial invitation letter. Their delayed availability may have impacted on the ability of schools to timetable in lessons for the new academic year and could have detracted from the engagement of schools with the requirements of the trial.

Note that the trial moved from a planned 'effectiveness' trial, where intervention schools are left completely to their own devices, to an 'efficacy' trial where NFER staff reminded schools to register for the programme, which could have altered results. Without being reminded, schools could have been even less likely to have delivered the programme with high fidelity. It is not possible to say to what extent external help altered fidelity but it is safe to say that the trial now represents a slightly exaggerated picture of how well schools might deliver the programme in reality.

A process evaluation was carried out as part of the trials to explore factors (including fidelity, views on programme content, and challenges faced in delivery) which could help to explain the quantitative results. Given difficulties faced with general recruitment to the trial, schools included in the process evaluation were those willing to take part (and thus are likely to be those most engaged with the programme). This, and the fact that only small numbers of schools and individuals were included in the qualitative element of the trial, means that the process evaluation results are *illustrative* and should not be generalised.

In order to do the planned cost-effectiveness analysis there would have needed to have been evidence of an effect of the programme in relation to outcomes of interest, which was not the case. In addition, we were not able to obtain the necessary expenditure data from case-study schools to have been able to conduct this analysis if an effect had been evident. For example, school staff were not able to quantify the amount of money spent on printing, photocopying and the amount of additional time over and above what they would have spent otherwise.

6.2 Interpretation and Discussion

Although the development of In:tuition was informed by evidence-based life skills programmes such as 'Unplugged', there are differences between the programmes and the measures of impact that mean the results are not directly comparable. For example, the content differs (Unplugged covers the broader issues of tobacco and illicit drugs) and the Unplugged programme incorporates two and a half days of training for teachers who will deliver it.

The main hypothesis that the primary school trial of In:tuition was designed to test was that the In:tuition programme improves resistance skills (confidence to manage peer pressure) in 10 and 11 year-olds. We conclude that there was no evidence of a positive impact on this primary outcome. There was no statistically significant difference between the intervention and control groups. This also means, though, that there was no evidence of any *negative* impact. No significant effects of the programme were found for different sub groups.

For the secondary school trial, the main hypothesis was to test that participation in the programme has an impact on the proportion of pupils aged 12-13 that are drinking frequently. Overall, there was no significant effect on frequency of drinking. However, In:tuition was found to work differentially for males and females. In the intervention group, males were more likely and females were less likely to be frequent drinkers compared to their counterparts in the control group at follow up. However, further research would need to be undertaken to determine if this was a genuine effect of the intervention. No other significant effects on sub-groups were found.

Impact on other secondary outcomes was also explored for both trials and there was little evidence of any effect of the programme. One exception was the impact on knowledge among primary school pupils. The results show that pupils in the intervention group had, on average, better knowledge about alcohol and its effects than those in the control group, although this result did not meet the p=0.05 threshold of statistical significance. This could be indicative of a genuine effect of the intervention on increased knowledge. Evidence from the process evaluation also suggested a perceived impact on pupils' knowledge. The literature review carried out by Martin *et al*. (2013) found most evidence of impact of other school-based alcohol education and life-skills programmes was on pupils' alcohol related-knowledge. The literature reveals variable or inconclusive evidence in relation to impact on young people's decision-making skills or drinking behaviour.

Evidence from the fidelity analysis and process evaluation indicates that not all teachers in the intervention group delivered the programme in its entirety – indeed some did not deliver it at all. Of those who did deliver lessons, views were generally positive about the programme's content and teaching approaches/activities included in lesson plans, although most teachers adapted the programme to reduce its length due to a lack of curriculum time to cover it all. This finding suggests that the recommendation resulting from the feasibility study (Barksfield and Hull, 2012) that steps should be taken to encourage better course fidelity, particularly by reducing the length of the programme, still stands.

Teachers tailored aspects of lesson delivery to the needs of their pupils. The lessons were thought to be of a good quality, yet too detailed and lengthy for the entire content to be covered. Moreover, only a minority of teachers who participated in the process evaluation had sent home *some* of the homework tasks for pupils to complete with their parents/carers – none had sent *all* of them home. Note that the review carried out by Martin *et al*. (2013) concluded that when parents and families had been included in interventions, results were usually positive. Again, this suggests that a recommendation resulting from the feasibility study, that parental engagement with the 'home learning' activities should be encouraged, still stands.

On-treatment analysis of the primary outcomes took into account the extent of programme fidelity among teachers in the trials. This did not result in any change in findings i.e. there was no positive (or indeed negative) impact on the primary outcomes (resistance skills in primary schools and frequency of drinking in secondary schools) depending on the extent of programme delivery. This indicates that the In:tuition programme is not meeting its stated aims.

To conclude, recruitment difficulties were faced, which was followed by school attrition (particularly in secondary schools) which could have had an impact on

results. There was little evidence of positive – or indeed negative - impact of the programme. Pupils in schools which delivered the intervention did no better – or worse – than those in schools doing their normal PSHE curriculum. Evidence from the fidelity analysis and process evaluation indicates that not all teachers in the intervention group delivered the programme in its entirety – indeed some did not deliver it at all. Moreover, the extent to which In:tuition was delivered in schools did not impact on this result. Although teachers saw some value in the individual elements of the programme, for the programme to have a positive impact in its *entirety* it needs fundamental revision.

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