PHR Protocol - project ref: 10/3002/09
Version: 2
Date: February 2012

Adaptation of SHAHRP (Schools Alcohol Harm Reduction Programme) and TATI (Talking to Children About Tough Issues) Alcohol Misuse Prevention Programme (STAMPP): a school based cluster randomised controlled trial

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Sponsor	Liverpool John Moores University (UK)
Funder	NIHR Public Health Research Programme
NIHR Portfolio number	10/3002/09
ISRCTN registration (if applicable)	ISRCTN47028486

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1. Aims/Objectives:

The overall research question to be answered is: Is a classroom psychoeducational intervention with parental components (STAMPP) (cost) effective in reducing hazardous drinking and the harms associated with alcohol use in young people compared with alcohol education as usual (EAU)?

This will be assessed by determining changes in several indicators of alcohol consumption, alcohol cognitions, and other alcohol related behaviour. Outcomes will be assessed using a variety of standardised and validated measures. The main objectives of the research are to determine:

- The (cost) effectiveness of STAMPP in reducing alcohol consumption (self reported alcohol use in lifetime, last year and previous month; number of drinks in 'typical' and last use episodes; frequency of consuming >5 drinks in a single episode in the previous 30 days; age of alcohol initiation) in year 9 pupils immediately post intervention, + 6 months and + 18 months after intervention.
- The effectiveness of STAMPP in reducing alcohol related harms as measured by health service utilisation and self-reported harms (harms caused by own drinking and that of others) in year 9 pupils immediately post intervention, + 6 months and + 18 months after intervention.

And, if shown to be effective:

- Which components of STAMPP make it effective in reducing alcohol related harm in year 9 pupils immediately post intervention, + 6 months and + 18 months after intervention?
- What are the behavioural and cognitive mediators of change (individual and family factors) that lead to the effectiveness of STAMPP in year 9 pupils immediately post intervention, + 6 months and + 18 months after intervention?

2. Background:

Adolescence is a period when young people increasingly begin to experiment with alcohol, and as they get older they increase their consumption both in terms of amount and frequency (Fillmore et al., 1988). Alcohol misuse among adolescents occurs in most countries worldwide (see for example Masterman & Kelly, 2003), and in England (no data is available for the rest of the UK but it is likely to be similar) it is estimated that 26.6% of male and 14.7% of all female deaths in young people aged between the 16 and 24 are attributable to alcohol use (Jones et al., 2008). Of particular concern is drinking to or beyond recommended adult daily limits, which is associated with short term negative outcomes including problems at school (e.g. truancy, exclusion, and poor attainment), unsafe sexual behaviour, unintended pregnancies, trouble with police and/or parents, accidents/injuries, aggressive behaviour and falling out with friends (e.g. Marlatt & Witkiewitz, 2002; Masterman & Kelly, 2003). Moreover, heavy drinking during adolescence has been suggested to have an influence on the probability of developing serious alcohol-related problems during adulthood such that those who begin drinking alcohol prior to age 14 are four times more likely to develop dependence than those who begin drinking at age 20 (Grant & Dawson, 1997). Adolescents are potentially more susceptible to the development of alcohol abuse problems as their brains are still developing (Spear, 2000). One study found that the clearest predictor of alcohol dependence in young adults was regular recreational alcohol use in the teenage years (Bonomo et al., 2004).

The Young Person's Behaviour and Attitudes Survey (YPBAS) (Northern Ireland Statistics and Research Agency, NISRA) is a self report survey which gathers data on a broad range of adolescent behaviours and attitudes, including those relating to alcohol. The 2002 YPBAS revealed that 59.5% of young people aged 11 to 16 had consumed an alcoholic drink, with abstinence decreasing with age so that 16.9% of 16 year olds were abstainers, with the largest percentage change between abstainer and lifetime user occurring between age 12 and 13 (NISRA, 2003). Alcohol use among girls has increased steadily in Northern Ireland so that while boys reported lifetime use of alcohol to a greater extent than girls in 1997 and 2000, by 2003 there was no significant gender difference. Data for 2000, 2003 and 2007 indicated that the median age of alcohol initiation was 12 to 13 years old (NISRA, 2000; 2003; 2007). By 2007 (NISRA, 2008), 76% of respondents reported that they had their first full alcoholic drink at or before age 13. Regarding frequency of use, in 2000 more than one in four 11-16 year olds reported drinking alcohol at least once per week and by 2008 this had risen to 36% (NISRA, 2000; 2008). Less than one in three reported lifetime drunkenness in 1992, and by 2003 this had risen to over half of young people questioned (Health Promotion Agency NI, 2005). Among those who reported getting into trouble as a result of drinking alcohol, 32% reported trouble with parents/family, 13% reported trouble with friends, 11% reported trouble with the police, 10% reported trouble with local people and 2% reported trouble with school (NISRA, 2008).

3. Need for the current study:

Reviews of effective school based alcohol prevention programmes for adolescents have failed to consistently identify interventions which are well designed, implemented, and properly evaluated (e.g. Jones et al., 2007; Foxcroft et al., 1997; Foxcroft et al., 2003; Nation et al., 2003; McBride, 2003; Faggiano et al., 2008); in their Cochrane Collaboration review of school based interventions, Foxcroft and colleagues (1997; 2003) were unable to recommend any one prevention initiative. However, one conclusion which is consistent across most reviews is that prevention efforts which utilise interactive multimodal approaches, usually knowledge, skills enhancement, and affective approaches appear to be superior in their impact to those which seek to enhance only knowledge (e.g. Foxcroft et al., 1997; Nation et al., 2003; Faggiano et al., 2008). In the absence of substantial evidence on particular programmes, guidance issued by the National Institute for Health and Clinical Excellence (NICE) in 2007 called for partnership working between schools and other stakeholders in efforts to prevent misuse. NICE also suggested that school based educational interventions should aim to increase knowledge about alcohol, explore perceptions about use, and help develop decision-making skills, self efficacy and self esteem. A recent Cochrane review examined 12 randomised controlled trials investigating the effectiveness of family-based universal programs for the prevention of alcohol misuse in young people (Foxcroft and Tsertsvadze, 2011). In family settings, universal prevention typically takes the form of supporting the development of parenting skills including parental support, nurturing behaviours, establishing clear boundaries or rules, and parental monitoring. Social and peer resistance skills, the development of behavioural norms and positive peer affiliations can also be addressed with these types of approach. Most of the studies included in the review reported positive effects and although small, were generally consistent and also persistent into the medium- to longer-term.

There is an extensive literature examining individual, societal, and population level risk factors for adolescent alcohol misuse, and mediators of behaviour change (e.g. Hawkins et al., 1992). In recent studies conducted by the research team, for example, strong associations were found in adolescents between time perception, consideration of the future consequences of behaviour, and self efficacy/esteem with levels of alcohol involvement (McKay et al., in press a, b, c). A number of studies (e.g. reviewed by Jones et al., 2007; Foxcroft et al., 2011; Foxcroft et al., 1997) have demonstrated that attitudinal and behavioural change is possible in those adolescent populations who have received alcohol interventions that target such factors, although the strength of association between these variables and changes in drinking behaviour

is often unclear. Family factors too are important in determining the nature and extent of adolescent alcohol use. These relate not only to the structure of families, but also family cohesion, family communication about issues such as substance use, parental modelling of behaviour (e.g. parental use of substances or rules on substance use), family management, parental monitoring supervision, parent/ peer influences, and availability of alcohol in the family home (Velleman, 2009).

School based substance education programmes in the UK have predominantly been concerned with primary prevention, aiming to delay onset of use (Parker and Eggington, 2002). However, unlike illegal drugs, it is not against the law for young people to drink alcohol, and in adult life, sensible drinking contributes to a happy and fulfilling social life with many benefits (Peele and Brodsky, 2000). Furthermore, although the Chief Medical Officer has called for an alcohol-free childhood up to the age of 15 (CMO, 2009), interventions which aim to prevent alcohol use completely are not supported by national policies (e.g. Safe Sensible Social, 2007). A more realistic approach to tackling alcohol misuse is not only to try and reduce the amount of alcohol that young people drink (i.e. hazardous drinking), but also to reduce the harms that they experience from all types of drinking (hazardous or otherwise); i.e. a 'harm reduction' approach to intervention. Harm reduction refers to programmes or approaches that specifically aim to decrease the harmful consequences of drinking without requiring abstinence as a necessary outcome (although a reduction in drinking is encouraged) (Masterman and Kelly, 2003). These harms can arise from both the actions of the drinker (e.g. accidents, health problems) and also from the drinking of others (e.g. drink driving, violence). Moreover harm reduction offers a viable method for attempting to persuade adolescent drinkers, who may be unaware of the harmful implications of consumption, to consider the immediate (and to a lesser degree more distant) negative outcomes of alcohol misuse. Among adolescents this approach may have added advantages including the fact that younger drinkers will not feel stigmatised, alcohol use will not be presented in a moral framework and harm reduction approaches can be tailored to address specific risk factors along the developmental trajectory of alcohol use in this population (Masterman and Kelly, 2003; Marlatt and Witkiewitz, 2002).

In school children a harm reduction approach is relevant as young people are having their first experiences of intoxication and although they may not always be drinking to hazardous levels, they are often drinking in unsupervised contexts and subject to the consequences of peers' drinking (Coleman and Carter, 2005).

The School Health and Alcohol Harm Reduction Project (SHAHRP), which is the core intervention being examined in this research is an example of an evidence based education intervention that aims to reduce hazardous drinking and alcohol harms. It combines a harm reduction philosophy with skills training, education, and activities designed to encourage positive behavioural change (McBride et al., 2000; 2004). It is a curriculum-based programme with an explicit harm reduction goal and is conducted in two phases over a two year period. As a harm reduction based intervention the programme does not explicitly aim to reduce alcohol consumption, although this may be a favourable consequence of exposure. In the original Australian programme evaluation the intervention group (compared to the controls) developed significantly greater knowledge at 8-month follow-up and this was maintained at 20 month follow up (McBride et al., 2004). By final follow up (32 months) the mean knowledge scores of both groups had converged. The intervention group developed significantly safer alcohol-related attitudes (attitudes which supported less harmful behaviours) from first follow-up at 8 months and this was maintained to the 32 month follow up point. There was a significant difference between the study groups in the self-reported harm they experienced from their own use of alcohol after both phases of the intervention. This was maintained 17 months after the intervention.

A recent pilot study utilising a non-experimental design conducted in Northern Ireland (McKay et al., in press d) showed that after appropriate adaptation (e.g. normative epidemiological facts

updated, timings of lessons altered), participation in SHAHRP was associated (across 32 months of follow up) with significant benefits for participants. Between groups comparison showed that intervention pupils reported significantly fewer alcohol harms across time, and when drinking behaviour trajectories were modelled using latent class growth modelling, intervention pupils were significantly more likely than pupils receiving education as normal to be in those latent classes reporting less increase in drinking over time. They were also members of latent classes that showed a large increase in alcohol knowledge and healthy attitudes, and were more likely to report either a smaller, or no increase at all in alcohol related harms.

Given the prevalence of underage drinking in the UK, the reported problems, costs and harms associated with this behaviour, and the lack of a robust UK evidence base for alcohol prevention we will investigate an adapted form of the evidence based SHAHRP programme (McBride et al., 2004) in a culturally appropriate and curriculum consistent manner in the Northern Irish and Glasgow post primary school context. Furthermore, considering the strong links between family behaviours and young people's alcohol use we will also examine the effects of introducing a parental component (TATI) to the core SHAHRP curriculum. Such work would provide a more experimentally robust validation of previous pilot work. If shown to be effective, STAMPP could be introduced into other schools across the UK as it lends itself well for inclusion in the PSHE curriculum.

4. Methods:

a. Setting
90 post primary schools in Northern Ireland and Glasgow

b. Design
A randomised controlled cluster trial comparing STAMPP vs alcohol education as normal for the reduction of hazardous and harmful alcohol drinking and alcohol related harms.

Inclusion: Male and female school children (Year 9; pupils aged at leats 13 on the 1st September 2012) and their parents/carers, attending post-primary secondary schools in NI and Glasgow.

Exclusion: Pupils not in the specified school year and ages. Pupils in non mainstream and vocational education (e.g. pupil referral units, further education colleges). Pupils with special educational needs are excluded at the discretion of teachers as the intervention materials have not been developed for use with this population.

c. Data collection

Assessment schedule:

Data will be collected at 4 time points; T1 (baseline), T2 (6 months post phase 1), T3 (+6 months post intervention), T4 (+18 months post intervention)

Child completed measures:

i) Period prevalence of alcohol use – self reported alcohol use in lifetime, last year and previous month
ii) Amount and frequency of episodic alcohol use – number of drinks in 'typical' and last use episode, frequency of consuming >5 drinks in a single episode in the previous 30 days
iii) The age of alcohol initiation – age at which a whole drink of alcohol was first consumed, not just a sip or a shared drink.

Outcomes i-iii: Quantity, frequency and period prevalence measures and definitions of use are taken from two major UK alcohol use in young people surveys; The European Survey Project on Alcohol and Other Drugs (ESPAD; www.espad.org), and Smoking, Drinking, and Drug Use in Young People (conducted by the National Centre for Social Research http://www.ic.nhs.uk/statistics-and-data-collections/health-and-lifestyles-related-surveys/smoking-drinking-and-drug-use-among-young-people-in-england).

These were all outcomes that were included in the original Australian (McBride et al., various dates) and pilot NI (McKay et al., in press) SHAHRP evaluations but have been adapted slightly to make them relevant to current UK alcohol policy (e.g. Healthy Lives Healthy People (2010); Drug Strategy 2010: reducing demand, restricting supply, building recovery (2010); New Strategic Direction for Alcohol and Drugs (NI, 2006); Youth Alcohol Action Plan 2008)

Secondary outcomes:

i)   Alcohol knowledge and attitudes

These are our main educational outcomes. In keeping with the findings of systematic reviews (e.g. Jones et al., 2007) we do not anticipate there to be a direct relationship between changes in knowledge/attitudes and alcohol use behaviour, but they may act as mediators. For example, there is often an inverse relationship between knowledge and drinking and research on social influences has found that information can be persuasive; and can change attitudes when individuals are sufficiently motivated to use the information (Chaiken, 1980; Petty & Cacioppo, 1986). Interestingly, there may also be a positive association between knowledge and self-reported drinking as heavier drinkers may be more likely to be interested in and retain knowledge about alcohol ('self reference effect'; Symons & Johnson, 1997). The inclusion of the attitudes scale will help us to determine the nature of this relationship. Generally, although Alcohol related knowledge will be measured using a 19 item knowledge index (internal consistency 0.73) (McBride et al., 2004). Attitudes will be measured using a six item scale (internal consistency 0.64) (McBride et al., 2004). The attitudes scale is scored so that a higher score reflects 'safer' attitudes.

ii)   Harm cause by own and others' alcohol use

Harms associated with own use of alcohol will be measured using a 16 item scale (internal consistency 0.9) (McBride et al., 2000). This is included to assess the relationship between alcohol use and self-reported medical attention or support in this population. Harms associated with other people's use of alcohol will be measured using a 6 item scale (internal consistency 0.7) (McBride et al., 2004). For both harm scales, participants are asked to indicate on a Likert scale how many times in the past year they had experienced the individual harm.

iii)   Un/supervised alcohol use – prevalence of drinking with peers with or without the supervision of parents/guardians.

This outcome relates to the context of alcohol use. McBride et al., (2003) showed that unsupervised drinkers who did not receive the SHAHRP intervention reported a significantly greater number of alcohol related harms than intervention students. Other studies have produced conflicting data on the benefits of un/supervised drinking, with some reporting that supervised drinking provides protection against harmful patterns (e.g. Bellis et al., 2007), whilst and others report that any type of adolescent drinking, regardless of whether this is supervised or not, leads to greater drinking over time, and a greater number of alcohol related problems (e.g. Van der Vorst et al., 2010). Inclusion of this outcome, measured longitudinally and with supplementary information on the context of un/supervised drinking (e.g. at a celebration, with the family meal, watching the TV) should help us to understand this relationship, and whether the intervention is differential effective according to use context.

Mediators of intervention effect: as we are interested in understanding the effects of the intervention on the targetted mediators of behaviour change, and how these are related to alcohol use, children's questionnaire pack also includes other validated and standardised self report assessments. For example, time perspective will be assessed using the Zimbardo Time Perspective Inventory (Zimbardo and Boyd, 1999); and self efficacy with the General Self Efficacy Scale (Schwarzer & Jerusalem, 1997).

Parent/carer completed measures:

Parents/carers will complete a short questionnaire which will be used in the planned mediation analyses and incorporate assessments of parenting style, family rules on alcohol, and opportunities to drink in the family environment as covariables.

Parental communication skills and parenting styles will be assessed using a composite score generated from the Warmth/Affection subscale (WAS) of the Parental Acceptance–Rejection Questionnaire (PARQ) (Rohner, 1991), and the Parenting Control Scale (Rohner, 1989).

The WAS assesses perceptions of the parental warmth of fathers (or primary male caregivers), and mothers (or primary female caregivers), and is a reliable measure of the extent to which parents/carers are loving, responsive, and involved in their child's life (α = 0.91-0.93).

The PCS is a valid and reliable 13-item self-report questionnaire that assesses adults' perceptions of the behavioural control they administer to their children. Meta-analysis and factor analyses of data have shown that the PCS is a reliable and valid measure for research purposes (α = 0.80-0.82) (Rohner & Khaleque, 2003). Calculation of the composite score allows categorisation of respondents into one of four parenting styles: authoritative, indulgent, authoritarian, and neglectful.

Other questions will assess parental/carer norms around alcohol use in young people and the establishment of alcohol specific rules in the family home (van der Vorst et al., 2006). Alcohol Rules is a 10-item scale to measuring the degree to which parents permit their children to consume alcohol in various situations, such as 'in the absence of parents at home' or 'at a friend's party' (α = 0.86-0.90).

The Alcohol Use Norms Scale (Brody et al., 1990) assesses the degree of perceived acceptability of various drinking behaviors for adolescents in the target age group Each item of the scale begins with the phrase 'How acceptable is it for a X-year-old boy/girl to…' followed by situations such as 'have a small glass of wine during a family dinner' or 'get drunk when drinking alone'. A higher score indicates more liberal norms toward the drinking of 13-year-olds. The internal consistency of this scale is good (α = 0.83-0.85).

Process and Qualitative data: Our process evaluation will run alongside the assessment of outcomes and will use multiple methods. Using a range of techniques developed during the research team's history of conducting process evaluation with young people's drug and alcohol services, standardised tools presented in the EMCDDA's Prevention and Evaluation Resources Kit (PERK) and Evaluation Instruments Bank[1], and frameworks such as those provided by Saunders, Parry- Langdon and their respective colleagues (2005; 2003) we will undertake a comprehensive assessment of the commissioning, delivery, outlook, and participation experiences of STAMPP. STAMPP will be partly assessed against published quality standards in drug prevention[2], which includes quality criteria with respect to aspects such as *Intervention*

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[1] http://www.emcdda.europa.eu/eib
[2] http://www.emcdda.europa.eu/themes/best-practice/standards/prevention

Design, *Management and Mobilisation of Resources*, *Delivery and Monitoring*, *Ethical Intervention*, *Workforce Development* and *Sustainability and Funding.*

Other assessments will include interviews with teachers, pupils, parents, and local policy makers. We are particularly interested in student responses to substance use education, particularly with respect to understanding the role that alcohol plays in their lives. Our parental survey will examine skills and rules developed around alcohol use, but more in depth focus group interviews will pose other important questions, such as how parents believe young people learn about alcohol drinking, and how parents can best be supported in family based health promotion in partnership with schools. Work with teachers and policy makers will look at professional aspects of the intervention, particularly with regards to sustainability and teachers' confidence and perceived ability in delivering the classroom components.

Contextual data:
Socioeconomic position of the school will be determined through postcode matching with IMD datasets held by public health observatories. Fidelity of implementation will be assessed using a bespoke tool designed for self-completion by teachers that will capture information on adherence; exposure and 'dosage'; quality; and perceived participant responsiveness; and differentiation In addition the pedagogic orientation and religious identity of the school will also be assessed.

d. Data analysis

Intervention outcomes: analysis and presentation of data will be in accordance with CONSORT cluster RCT guidelines (Campbell et al., 2004).

1. Assessing trial validity
Initial data analysis will examine the extent to which the necessary conditions required to permit a valid test of the treatment efficacy have been met (see Del Boca & Darkes, 2007). This will include assessment of achieved statistical power, patterns of attrition, between group equivalence across the trial arms, and treatment integrity and discriminability (i.e. that SHAHRP was sufficiently distinct from education as normal) across the various sites. This work will include analysis of both qualitative and quantitative data.

2. Testing treatment effectiveness
ITT analysis: The initial outcome analysis will be an *intention-to-treat analysis* (ITT) such that all cases will be assessed regardless of intervention and intervention dosage. However, as the study design is clustered (i.e. randomisation occurred at the school level) the lack of independency between individual cluster members must be taken into account to avoid underestimated standard errors (which inflate statistical significance). As a result this initial ITT analysis will be conducted at the cluster level using summary measures and at the pupil level with test statistics adjusted for intracluster correlation (see Campbell et al., 2000; Lancaster et al., 2010).

Inclusion of covariates: In addition to the initial ITT, multivariate (regression) models will be estimated to examine the impact of covariates on intervention outcomes. Baseline outcome measures will be included as covariates to allow for individual differences. Including information on covariates will allow us to examine moderator effects and to begin to unpack the mechanisms through which SHAHRP and the parental component might impact on desired outcomes. Here, model estimates with standard errors that are robust to the non-normality and non-independence of observations will be computed (for example, Mplus employs a sandwich estimator to compute robust standard errors under the TYPE=COMPLEX option).

A key part of this analysis will be to try to minimise the unexplained variance in site-specific

effects. This will increase power and, by capturing the factors that explain why effects vary across sites (e.g. differences in parental recruitment and attrition; differences in implementation fidelity), will help in generalising the results beyond the study sites. Thus we will look at possible sources of variation across sites in each arm, in particular, in what constitutes education as normal trial arm.

Multilevel growth models: Finally, we intent to use multilevel growth modelling to test the hypothesis that participation in the interventions will lead to reduced *growth* in the specified primary and secondary alcohol outcomes over time compared to students in the education as normal trial arm. This will extend the modeling work undertaken at previous stages. We also hypothesise that children whose parents receive the additional parental component will report better outcomes than those that receive the intervention without the parental component and those children that receive education as normal.

Treatment of missing data: Examination of missing data (both case and item) will be undertaken on outcomes measures and covariates. Depending on the result of this, multiple imputation methods (Schafer, 1997; Schafer & Graham, 2002) may be employed to reduce biases due to any missing responses within the ITT analysis (Little & Yau, 1996). Consideration will also be given, where appropriate, to modelling strategies that generate robust standard errors in the presence of missing data (i.e. FIML).

Sensitivity analysis: Analysis will be undertaken to assess the robustness of the outcome analysis. This will include the repetition of the analysis on alternative specification of outcomes measures, different subsets of the study population (i.e. per protocol analysis), and with different missing data models.

3. Examining treatment processes: how, why and for whom treatment works
If feasible (e.g. if statistical power is sufficient), analysis will be undertaken to test potential mechanisms through which observed treatment effect may have occurred. Two domain growth modelling approach for longitudinal data, in which the growth curves of the outcome and the mediator are estimated simultaneously, will be employed to examine potential mediation processes.

In addition, analysis will be undertaken to identify potential subgroup differences in treatment response. If appropriate, we will also employ multilevel mixture models (see for example, Van Horn et al., 2008) to explore the possibility that the preventative intervention has a differential effect across different sub-groups (latent classes) of young people. This includes the possibility that the intervention affects low level users differently than more serious hazardous drinkers.

All statistical analyses will be conducted using software packages such as MPlus 6.1 (Muthén & Muthén; license requested in costings), Latent Gold 4.5 (Statistical Innovations) and PASW 18 (IBM/SPSS)

4. Health economic analysis

A within-trial cost effectiveness analysis (CEA) will be undertaken to assess the cost-effectiveness of STAMPP compared with usual education in preventing hazardous drinking of alcohol by school aged children. A societal perspective will be adopted for the analysis capturing resource use data related to each child's contact with the National Health Service (NHS), Personal Social Services (PSS), social services and criminal justice service directly as a result of their alcohol consumption. Data on resource use by all participants over the course of the study and follow up period will be collected using questionnaires for completion by the participant. We intend to use a known instrument such as the Client Service Receipt Inventory (CSRI), modified where necessary for this population and to include questions relating to the use of judicial services. Intervention costs will also be measured. These will include the costs

associated with staff training and delivery of the intervention.

Resource utilisation over the 18 month study period will be quantified and unit costs will be applied from national sources. These will be derived from the National Health Service (NHS) reference costs, the Personal Social Services Research Unit's (PSSRU) Unit Costs of Health and Social Care and Unit Costs of Criminal Justice. Although the NHS reference costs are based on data derived from England and Wales only, they are readily available and up-to-date. The Department of Health and Social Services and Public Safety (DHSSPS) in Northern Ireland do publish reference costs, but these tend not to be up to date (2007/08 reference costs were just published in January 2010). The National Health Service Scotland (NHSS) do not have the level of detailed HRG costing that exists in the rest of the UK; costs are collected and published at specialty level only. Where national costs are not available, unit costs will be identified in consultation with the appropriate finance departments of the resource provider.

Consistent with the research question and the primary outcome of the study, the health outcome of interest for the economic analysis is the number of heavy episodic drinking episodes in the previous 30 days (i.e. drinking 5 or more drinks in a single episode). This will be measured via the standard questionnaires administered over the course of the study. We intend to use the area under the curve method to obtain a summary measure of hazardous drinking episodes over the 18 month period. An incremental cost effectiveness ratio (ICER) will be calculated to estimate the cost per case of hazardous drinking averted. This is in keeping with NICE public health guidance 7 (2007) "*Interventions in schools to prevent and reduce alcohol use among children and young people*" in which cost per case of hazardous/harmful drinking averted was chosen as the primary measure of cost and effect in the review of the economic evaluations in this area. To account for uncertainty due to sampling variation in cost-effectiveness measures a cost effectiveness acceptability curve (CEAC) will be plotted showing the probability of the intervention being more cost-effective than usual education at different threshold levels of willingness-to-pay (WTP) to avert a case of hazardous drinking. Although there is no generally accepted cost per case of hazardous drinking averted threshold value (unlike NICE's QALY threshold), we intend to compare our findings with those of other economic evaluations which have been performed in this research area. Since the time horizon of the analysis will extend beyond 12 months, the costs and benefits accrued will be discounted to reflect their present value. Sensitivity analysis will be performed to explore the impact on cost-effectiveness of variations in key parameters. This will align closely with the sensitivity analysis planned in the main study e.g. different subsets of the study population. The results will be presented as CEACs. Long-term modelling of the results may take place but only after completion of the trial and it would be commissioned separately.

5. Contribution of existing research:

Few evaluations of UK alcohol interventions have been subject to high quality research designs. This study will provide a robust analysis of the effectiveness of a new alcohol education model in the UK. The work will build upon previous pilot work on the classroom component of STAMPP (McKay et al., in press d) but will this time utilise an RCT design, include a parental component, have greater statistical power, include long term follow ups (+18 months), include costs effectiveness modelling, and an assessment of intervention mediators.

6. Plan of Investigation:

Month (milestone begins)	Milestone
-3	Recruitment of 2 x researchers
0	Study begins
2-3	Ethical approval sought and obtained
3-6	Recruitment of school gatekeepers; convening of first Trial Steering Committee
5	Preparation of study materials
6	Piloting (pre-testing) and refinement of study materials (e.g. questionnaires, administration protocol)
7	Randomisation of schools
8-11	Training of teachers and parental workers by intervention staff (External non-funded activity)
9	Baseline survey
11	Data entry, cleaning, and analysis of baseline data begins
12-15	Phase 1 intervention delivery
15	Phase 1 survey
19	Data entry and analysis baseline→ end of phase 1
24-27	Phase 2 intervention delivery
21	Refinement of Phase 2 study materials (if required)
27	Phase 2 survey
29	Phase 2 data entry and analysis begins
31	Analysis of data phase 1→ phase 2
33	6 month follow up survey
45	18 month follow up survey
45-51	Analysis of data
51	Research ends, submission of final project report to NIHR

7. Project Management:

There are two main management committees:

Trial Steering Committee (TSC): steered by an independent chair and meeting annually the TSC will be responsible for monitoring recruitment and attrition at the different points of data collection, to advise on ethical matters, for ensuring that the delivery of the intervention and data collection is conducted in a manner which is considerate of the needs of individual schools, and for ensuring that the data analyses are disseminated in an appropriate manner. It is envisaged that the TSC will meet before each phase of the intervention and before each of the scheduled data collection periods.

Trial Management Group (TMG): the TMG comprises the investigators, appointed researchers (trial manager and researcher) and departmental contract managers. The group will be tasked with overseeing the operational running and process of the project. The group will be chaired on a rotating basis and will meet at least quarterly.

8. Service users/public involvement:

Throughout the research, and as part of the process evaluation, we will consult with young people and teachers (through group discussions, interviews and dissemination events) in order to seek feedback on their experiences in taking part in the research and intervention. Pupils also

have the opportunity to help the research team construct the study materials and information sheets. Secondly, we have representation of non-academics on our Trial steering committee. Thirdly, through development of existing links with health education and substance use prevention organisations such as the Drug Education Forum, EUSPR, and Mentor UK the applicants will take every opportunity to discuss the work and its findings with practitioners, policy makers, pupils, parents, and teaching staff. We will also collaborate with the NI and Glasgow educational boards to support the professional development of teachers through participation in training days, workshops and conferences. Communication of this research (as with the groups' previous work) will adhere to evidence based principles of dissemination (Bywood et al., 2008). Briefing materials will not just focus on the results of the trial, but also principles of evidence based alcohol prevention and the most effective ways that teachers and parents can support development of healthy alcohol behaviours. Dissemination media will also vary, including, for example, a project webpage, webcasts, and downloadable materials.

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