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Steps towards alcohol misuse prevention programme (STAMPP): a school and community based cluster randomised controlled trial

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Steps towards alcohol misuse prevention programme (STAMPP): a school and community based cluster randomised controlled trial

1. Aims/Objectives:

The overall research question to be answered is: Is a classroom psychoeducational intervention with a parental component (STAMPP) (cost) effective in reducing hazardous drinking and the self-reported 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 primary research objectives are:

- To ascertain the effectiveness and cost-effectiveness of STAMPP in reducing alcohol consumption (defined as self-reported consumption of ≥6 units in a single episode in the previous 30 days for males and ≥4.5 units for females) in school pupils (school year 9/S2 in the academic year 2012/2013) at + 33 months (T3) from baseline. This will be dichotomised at never/one or more occasions.

- To ascertain the effectiveness of STAMPP in reducing alcohol related harms as measured by the number of self-reported harms (harms caused by own drinking) in school pupils (school year 9/S2 in the academic year 2012/2013) at +33 months (T3) from baseline.

Secondary research objectives are:

- To ascertain the effectiveness and cost-effectiveness of STAMPP in reducing alcohol consumption (defined as self-reported consumption of ≥6 units in a single episode in the previous 30 days for males and ≥4.5 units for females) in school pupils (school year 9/S2 in the academic year 2012/2013) at +12 months (T1), + 24 months (T2) from baseline. This will be dichotomised at never/one or more occasions.
- To ascertain the 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; age of alcohol initiation, unsupervised drinking) in school pupils (school year 9/S2 in the academic year 2012/2013), at +12 months (T1), +24 (T2) months and + 33 (T3) months.
- To ascertain the effectiveness of STAMPP in reducing alcohol related harms as measured by self-reported harms caused by own drinking at +12 months (T1) and +24 months (T2), and self-reported harms caused by the drinking of others at +12 months (T1), +24 (T2) months and + 33 (T3) months, in school pupils (school year 9/S2 in the academic year 2012/2013).

The primary end point of the study is +33 months (T3) from baseline. The secondary endpoints are +12 months (T1) and +24 months (T2) from baseline.

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; 2007). 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, 2007).

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 Carel 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 behavioural 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., 2011a; 2011b; 2012). A number of studies (e.g. reviewed by Foxcroft et al., 1997; Foxcroft et al., 2011; Jones et al., 2007) 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 can contribute to a happy and fulfilling social life (Peele and Brodsky, 2000). Furthermore, although the Chief Medical Officer has called for an alcohol-free childhood up to the age of 15 (Donaldson, 2009), interventions which aim to prevent alcohol use completely are not supported by national policies (e.g. Safe Sensible Social, 2007; The Government's Alcohol Strategy 2012). A more realistic approach to tackling alcohol misuse may therefore be not only to try and reduce the amount of alcohol that young people drink, but also to reduce the harms that they experience from all types of drinking; 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, and the choice to be abstinent is

valued and supported) (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 or harmful 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 primary prevention is not the main outcome, 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., 2012) showed that after appropriate adaptation (e.g. normative epidemiological data 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 more positive 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 (Velleman, 2009) we will also examine the effects of

introducing a brief intervention (BI) delivered to parents to the core SHAHRP curriculum. The BI is a UK adaptation of a parental intervention trialled by Koning and colleagues (2010) in the Netherlands, itself an adaptation of the Swedish Örebro Prevention Program (ÖPP). Previous research has shown that when delivered in combination with a school-based alcohol curriculum (the Dutch Healthy School and Drugs programme), BI participation was associated with a significantly reduced rate of frequency of drinking or weekly drinking, partly mediated by changes in parental rules and attitudes towards alcohol (Koning et al., 2009; 2010).
If shown to be effective, STAMPP could be introduced into other schools across the UK as it lends itself well for inclusion in the health and citizenship curriculum.

4. Description of the intervention

Control schools will continue with their normal activities, including any alcohol education. Bespoke data collection tools will be used to collect information on alcohol education delivered in addition to statutory curriculum requirements. The intervention is delivered by trained teachers. Phase 1 of STAMPP is delivered when pupils are in year 10 (age 13-14), coinciding with the onset of alcohol use for many children, and phase 2 in year 11 (age 14-15), when alcohol use becomes more established. Phase 1 consists of six sessions (with 16 activities) and phase 2 consists of four sessions (with 10 activities). Each lesson incorporates skills-based activities and individual and small group discussions to emphasise the identification of alcohol-related harm and the development of harm reduction strategies. Interactive involvement is a key feature of the sessions.

The BI delivered to intervention children's parents comprises a short standardised presentation delivered by a trained facilitator to parents/carers at special parent evenings. The presentation includes information on alcohol prevalence in young people, corrects parents' (under)estimates of youth drinking, and highlights the importance of setting strict family rules around alcohol, with the recognition that children often model their own alcohol use behaviour on their parents/guardians. The presentation is followed by a brief discussion on family rules, and followed up by a posted leaflet providing a summary of the key information from the evening.

5. Methods:

a. Setting
105 post primary schools in Northern Ireland and Glasgow/Inverclyde Education Authority areas.

b. Design
A Clustered Randomised Controlled Trial comparing STAMPP vs alcohol education as usual for the reduction of hazardous and harmful alcohol drinking and self-reported alcohol related harms.

Inclusion: Male and female school children (school year 9/S2 in the academic year 2012/2013) and their parents/carers, attending post-primary secondary schools in NI and Glasgow/Inverclyde Education Authority areas.

Exclusion: Pupils not in the specified school year and age group. 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.

***Sample size calculation*:** Assuming a two level model (pupils at level 1 and school at level 2), a small effect size (δ=0.2), 80 pupils per school, and an ICC of 0.09, then 80% power would be achieved with a total number of 90 schools (45 in each study arm). This equates to a total level one sample size of 7200 pupils at baseline.

Randomisation: Randomisation will be performed at the level of the school. Two schools which were in very close geographical proximity, and as result shared staff and facilities, are treated as one unit to avoid contamination. Two schools which had shared pastoral care arrangements are also treated as one unit to avoid contamination. Stratified randomisation will be used to balance the arms and will be performed separately for Glasgow/Inverclyde and NI. Schools in Glasgow/Inverclyde will be stratified based on Free School Meal Provision (FSM; low / moderate/ high), which is taken as a proxy for socio-economic status. As a larger number of schools will be recruited in Northern Ireland, two stratification factors will be identified: FSM (low / moderate / high) and School-type (male / female / co-educational).

The statistician will be supplied with code numbers for schools and so blinded to school identity. Randomisation will be conducted as an electronic 'card sort'. Within each strata each school has a random number {rand() function in Excel} attached. The schools are then sorted by ascending random number and this process is repeated several times by holding down the refresh formula function key (F5/F9 depending upon Excel version). This makes it impossible to view intermediate allocations and the final order is taken as the school allocation.

c. Data collection

Assessment schedule:

Baseline: Baseline data is collected after randomisation (T0; month 0, baseline)
Follow-up visits: Adolescent participants are followed up after + 12 months (T1), + 24 (T2) and + 33 (T3) months from baseline.

Data collection will be undertaken by study researchers, who are independent of intervention delivery (teachers and prevention workers).

Child completed measures:

i) Heavy episodic alcohol use – number of units (standard drinks) of alcohol in 'typical' and last use episode; self-reported consumption of ≥6 units in a single episode in the previous 30 days for males and ≥4.5 units for females
ii) Self-reported harms resulting from alcohol drinking (harms caused by own drinking and harms experienced as a result of the drinking of others)
iii) Period prevalence of alcohol use – self reported alcohol use in lifetime, last year, last six months and previous month
iv) The age of alcohol initiation – age at which a whole drink of alcohol was first consumed, not just a sip or a shared drink.
v) Frequency of lifetime (self-defined) drunkenness, and age off first drunkenness.
vi) Context of use, (e.g., abstention, unsupervised drinking (prevalence of drinking without the supervision of parents/guardians), or supervised drinking.
vii) Parental rules on drinking

viii) Alcohol knowledge & attitudes.
ix) Sensation seeking
x) Three domains of self efficacy (academic, social and emotional)
xi) Schools were randomly allocated into five groups to complete one of the following: Stress/Loneliness & Perfectionism; Alcohol Outcome Expectancies; Time Attitudes; Alcohol Norms & Aggression; and Parental Attachment
xii) Support service utilisation for use in the health economics analysis

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 the measures that were included in the original Australian (McBride et al., 2000; 2003; 2004) and pilot NI (McKay et al., 2012) SHAHRP evaluations but have been adapted to make them relevant to current UK alcohol policy (e.g. UK Chief Medical Officers' guidelines on alcohol use in young people and children (Donaldson, 2009). 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).

Alcohol knowledge and attitudes: These are our main educational measures. 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). 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. 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 towards alcohol.

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.

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 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 differentially effective according to use context.

The primary outcome measures for assessing intervention effectiveness is:

i) Self reported alcohol use (consumption of ≥6 units in a single episode in the previous 30 days for males and ≥4.5 units for females) assessed at +33 months (T3) from baseline. This will be dichotomised at never/one or more occasion.
ii) The number of self-reported harms (harms caused by own drinking) assessed at +33 months (T3) from baseline.

The secondary outcome measures are:

i) Self reported alcohol use (self-reported consumption of ≥6 units in a single episode in the previous 30 days for males and ≥4.5 units for females) assessed at +12 months (T1) and +24 months (T2) from baseline. This will be dichotomised at never/one or more occasion.
ii) The number of self-reported harms (harms caused by own drinking) assessed at +12 months (T1) and +24 months (T2) from baseline.
iii) Self reported alcohol use (lifetime, last year and previous month) assessed at +12 months (T1), +24 months (T2) and +33 months (T3) from baseline.
iv) Support service utilisation assessed at +12 months (T1), +24 months (T2) and +33 months (T3) from baseline.
v) The number of self-reported harms caused by the drinking of others assessed at +12 months (T1), +24 months (T2) and +33 months (T3) from baseline.
vi) Age of alcohol initiation (age at which a whole drink of alcohol was first consumed, not just a sip or a shared drink) assessed at +12 months (T1), +24 months (T2) and +33 months (T3) from baseline.
vii) Unsupervised alcohol use (prevalence of drinking with peers without the supervision of parents/guardians) assessed at +12 months (T1), +24 months (T2) and +33 months (T3) from baseline.
viii) The number of drinks consumed in a 'typical' and the last use episodes assessed at +12 months (T1), +24 months (T2) and +33 months (T3) from baseline.

<u>Mediators of intervention effect</u>:
As we are interested in understanding the effects of the intervention on the targeted 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 Adolescent Time Attitudes Scale (Worrell et al., 2013), and self-efficacy with the Self Efficacy Questionnaire – Children (Muris, 2001).

Parent/carer completed measures:
Parents/carers will complete a short questionnaire which will be used in the planned mediation analyses and incorporate assessments of family rules on alcohol, and parental self-efficacy in implementing rules and controlling adolescent behaviour.

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) (van der Vorst et al., 2006).

Parental self efficacy is a three item scale assessing the level of confidence a parent has in their own ability to prevent their child from drinking (α = 0.67) (Koning et al., 2013).

Process evaluation:
The process evaluation is based upon the framework developed by Grant et al., (2013) for cluster randomised trials and will run alongside the assessment of outcomes. In accordance with this framework, the process evaluation will collect and report data in the following domains: 1. Recruitment of clusters; 2. Delivery to clusters; 3. Response of clusters; 4. Recruitment and reach in individuals; 5. Delivery to individuals; 6. Response of individuals; 7. Maintenance and policy context; 8. Unintended consequences. Data will be collected through a mixture of monitoring exercises and qualitative work with pupils, teachers, and other stakeholders.

Contextual data:
Socioeconomic position of the school will be determined through free school meal allocation. 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.

Blinding:
Neither teachers nor field researchers are blinded to the intervention delivered. All interim and final statistical analysis will be conducted on blinded data (at both the individual and school level).

d. Data analysis

i) Descriptive analysis

Summary statistics on school and pupil recruitment, withdrawal and dropout will be collated for both trial arms and form the CONSORT flow diagram for reporting of cluster randomised trials.

Intra-class Correlation Coefficient (ICC): ICC for the primary outcomes will also be calculated and included in the report of the trial. This will be calculated overall and for both arms separately.

Fidelity test: Appropriate descriptive analysis will examine the extent to which the necessary conditions required to permit a valid test of the treatment efficacy have been met. This will include assessment of achieved statistical power, patterns of attrition, and treatment integrity and discriminability (i.e. that STAMPP was sufficiently distinct from education as normal) across the various sites. This work will

include analysis of both qualitative and quantitative data.

Randomisation check: Descriptive summaries of baseline participant characteristics from the two trial arms will be tabulated to assess between group equivalence across the trial arms (check on randomisation). Descriptive data will also be tabulated to compare attendees at the parental session to those who complete the follow up questionnaire only. Descriptive summaries will also be produced for baseline data at school level. These data will be used to check comparability between study arms and generalisability of the study population.

Outcome measure scores from the questionnaires will be summarised and tabulated for the trial arms. Descriptive statistics with confidence intervals where appropriate will be used for the tabulation of outcomes in the trial arms. Confidence intervals presented will be adjusted to allow for clustering effects. Graphical illustration (including box plots, histograms and bar charts) will be used where appropriate and the distributions of all outcome measures will be checked.

ii) Analysis of primary outcome

The initial outcome analysis will be an intention to treat analysis (ITT) using the complete case (CC) population 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). For each primary outcome a two-level regression model will be fitted, with pupils nested within schools, to assess the impact of the STAMPP on the outcome measures. For self-reported consumption of ≥6/≥4.5 units, the model will be a logistic regression. For the number of self-reported harms, the model will be a Poisson regression. If the number of harms (count data) is over-dispersed, we would consider a Negative Binomial regression model for this outcome.

The primary outcome model will be adjusted for the impact of covariates on intervention outcome. Covariates to be included in the models include those used within the randomisation process (sex and SES), baseline outcome measures (consumption of ≥6 units and number of self-reported harms depending on outcome) and location (NI/Scotland). For each primary outcome, a statistical significant result will be concluded if the p-value for the trial arm explanatory variable is <0.025.

iii) Analysis of secondary outcomes

Differences in self-reported alcohol use (defined as self-reported consumption of ≥6 units in a single episode in the previous 30 days for males and ≥4.5 units for females - dichotomised) at +12 months (T1), and +24 months (T2) will be assessed using a two-level logistic regression model with covariates (baseline alcohol use, sex, SES and location). Similar models will be constructed for self-reported alcohol use in lifetime, last year and previous month (all dichotomised) and for unsupervised alcohol use (drinking without the supervision of parents/carers - dichotomised) at +12 months (T1), +24 months (T2) and +33 months (T3).

A two level Poisson model with covariates (baseline harms, sex, SES and location) will be estimated for the number of self-reported harms (harms caused by own drinking) at +12 months (T1), +24 months (T2). Similar models will be estimated for the number of self-reported harms caused by the drinking of others and the number of drinks consumed in a 'typical' and the last use episodes at +12 months (T1), +24 months (T2) and +33 months (T3). If these secondary outcomes are over-dispersed,

we would consider the use of a Negative Binomial model

Time to alcohol initiation (age at which a whole drink of alcohol was first consumed, not just a sip or a shared drink) at +12 months (T1), +24 months (T2) and +33 months (T3) will be compared between trial arms by estimating a two-level Cox proportional hazards model in those who had not already initiated alcohol consumption at baseline. The model will control for sex, SES and location.

iv) Subgroup analyses

To explore differential treatment effects on the primary and secondary outcome measures, interaction terms will be fitted between trial arm and baseline measures thought to predict the effect of treatment.

These include:

- Age, in months, of pupil at baseline;
- Sex;
- Socioeconomic status (using the proportion of free school meals indicator);
- Alcohol use behaviour at baseline – age of initiation, use of alcohol in the year prior to baseline, context of use (abstainer/supervised/unsupervised);
- and in Northern Ireland, a Grammar/Secondary school analysis.

Subgroup analyses will also be performed to test hypotheses generated from the process evaluation. These will be specified in a later version of the DAP before any trial analysis takes place, and will be generated by individuals with no access to the trial outcome data.

v) Health economic evaluation

A within-trial cost effectiveness analysis (CEA) will be undertaken to assess the cost-effectiveness of STAMPP compared with usual education in reducing heavy episodic (defined as self-reported consumption of ≥6 units in a single episode in the previous 30 days for males and ≥4.5 units for females; dichotomised at never/one or more occasion) drinking in second form pupils (aged at least 13 on the 1st September 2012) at + 33 months (T3) and +12 months (T1), and + 24 months (T2). It will adhere to the National Institute for Health and Care Excellence (NICE) guide to methods of technology appraisal (NICE, 2013), where appropriate.

Measurement of service use: 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) and criminal justice service. Data on service use by all participants from baseline (T0) to +33 months (T3) will be collected using an instrument (Appendix 1) administered at four time points which incorporates items taken from the Client Service Receipt Inventory (CSRI; Beecham & Knapp, 1992) specifically adapted for childhood (Knapp et al., 1999) and items relating to the use of judicial services. The instrument includes an information page with definitions of some of the public services in case the students were unfamiliar with them. The instrument was designed with input from relevant professionals (e.g. educational psychologist, social workers, Scottish and Northern Irish teachers) and reviewed by a social researcher experienced in delivering questionnaires to children, and other health economists. The instrument asks participants to report their use of services in the previous 6 months, therefore data will be linearly interpolated over the

study period to fill in gaps in survey periods and allow for total costs to be estimated (Siedl et al., 2012). Intervention costs will also be measured. These will include the costs associated with staff training, delivery of the intervention, travel and consumables.

Costing method: Pupil service use and intervention related resource use from baseline (T0) to +33 months (T3) will be quantified as outlined above and unit costs will be applied from national sources such as 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. Where national costs are not available, unit costs will be identified in consultation with the appropriate finance departments of the resource provider.

Measurement of effectiveness: Consistent with the primary outcome of the study, the primary economic effectiveness measure is the number of pupils who report heavy episodic drinking at + 33 months post baseline (T3). The secondary economic effectiveness measure is the number of heavy drinking episodes at + 33 months (T3). The latter will be calculated using data on the frequency of heavy drinking episodes in the previous 30 days collected at the four survey time points; baseline, +12 months (T1), +24 months (T2) and + 33 months (T3). Data will be linearly interpolated over the study period to fill in gaps in survey periods and obtain an estimate of the number of heavy drinking episodes over the study period.

Discounting: When assessing the cost-effectiveness of STAMPP it will be necessary to apply an appropriate discount rate to both costs and effects to reflect their present value since the time horizon extends beyond a 12 month period. The annual rate currently recommended by NICE (2013) is 3.5% for both costs and effects.

Cost-effectiveness: Incremental cost effectiveness ratios (ICERs) will be calculated. The ICER is a measure of the additional cost per additional unit of effect produced by one intervention compared with another. The primary CEA analysis will estimate the incremental cost per young person experiencing heavy episodic drinking avoided due to STAMPP at +33 (T3) and +24 months (T2). The secondary analysis will estimate the incremental cost per episode of heavy drinking avoided due to STAMPP at +33 (T3) and +24 months (T2). Multiple regression models will be used to predict costs and effects adjusted for covariates. Cluster RCTs raise analytical issues for CEA; costs in particular may be more similar within, rather than between, clusters. CEA should recognise both that costs and effects are correlated and that individuals are clustered within settings. Thus appropriate models will be used which recognise the clustered nature of the data (Grieve et al., 2010).

Sampling uncertainty: Uncertainty in the cost-effectiveness measures will be investigated using nonparametric bootstrapping with 1000 replications of the incremental cost-effectiveness ratios (ICERs). The resulting replicates will be plotted on the cost-effectiveness plane and used to construct cost-effectiveness acceptability curves (CEACs). The curves for the primary CEA will show the probability of STAMPP being more cost-effective than usual education at different threshold levels of willingness-to-pay (WTP) to avoid a young person experiencing an episode of heavy drinking at (i) +33 months (T3) and (ii) +24 months (T2). The curves for the secondary CEA will show the probability of STAMPP being more cost-effective than usual education at different threshold levels of willingness-to-pay (WTP) to avoid an episode of heavy drinking (i) +33 months (T3) and (ii) +24 months (T2). Although there is no generally accepted threshold value for cost per young person experiencing heavy episodic drinking avoided or cost per heavy drinking episode avoided we will compare our findings with those of other economic

evaluations which have been performed in this research area.

Sensitivity analysis: The robustness of the CEA findings will be assessed. This will include testing the sensitivity of the estimates to model specifications by re-estimating the multiple regression models and exploring different methods of dealing with missing data. Since a linear time trend will be assumed between data time points this may lead to costs and effects being under / over-estimated if said trend is not appropriate, thus we will also explore the impact of small increases / decreases in costs and effects.

6. 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., 2012) but will utilise an RCT design, include a parental component, have greater statistical power, include long term follow ups (+33 months), and include cost effectiveness analysis.

7. Plan of Investigation:

Date	Milestone
Nov 11	Study begins
Nov 11	Ethical approval sought and obtained
Nov 11-Jan 12	Recruitment of school gatekeepers; convening of first Trial Steering Committee
Feb 12	Preparation of study materials
Mar-Apr 12	Piloting (pre-testing) and refinement of study materials (e.g. questionnaires, administration protocol)
Apr 12	Randomisation of schools
Jun 12	Training of teachers by intervention staff
Jun 12	T0: Baseline survey completed
Jul 12 – Jun 13	Data entry, cleaning, and analysis of baseline data begins
Sep – Dec 12	Phase 1 intervention delivery (classroom)
Mar – Jun 13	T1: Post intervention Phase 1 survey
Jan – Feb 13	Adaptation and piloting of parental BI
Jul 13	Training of parental BI facilitators
Jul 13 – Feb 14	Data entry and analysis baseline→ end of phase 1
Sep 13 – Dec 13	Phase 2 intervention delivery (classroom and parent BI)
Jun 14	T2: + 24 months (post baseline) survey
Feb 15	T3: + 33 months (post baseline) survey
Mar 15 – Mar 16	Data entry, cleaning, and analysis of outcome data
Mar 16	Research ends, submission of draft final project report to NIHR

7. Project Management:

There are two main management committees:

Study Steering Committee (SSC): steered by an independent chair and meeting at least annually the SSC 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.

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-academic co-optees on our Trial Management Group. Thirdly, through links with health education and substance use prevention organisations, 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/Inverclyde educational boards to support the professional development of teachers through participation in training days, workshops and conferences.

9. Regulatory issues

9.1 Ethical approval
Ethical approval for the study was given by Liverpool John Moores University Research Ethics Committee (REC) [11/HEA/097] on 9th February 2012

9.2 Indemnity
Liverpool John Moores University will provide indemnity and compensation in the event of a claim by, or on behalf of participants, for negligent harm as a result of the study design and/or in respect of the protocol authors/research team.

9.3 Study sponsor
The study sponsor is Liverpool John Moores University

9.4 Funding
The trial is funded by the National Institute for Health Research Public Health Research Programme. The grant awarded was £1,044,370.00

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