

Steps Towards Alcohol Misuse Prevention Programme (STAMPP): a school- and community-based cluster randomised controlled trial

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Scientific summary

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Scientific summary

Background

The prevalence of alcohol use in young people in the UK is among the highest in Europe. Although rates of use have fallen in recent years, there are still concerns about the acute and long-term harms that result from adolescent alcohol use. Some universal school, family or multicomponent prevention programmes have been shown to be effective in reducing alcohol use in young people, but few of these have been rigorously evaluated in the UK.

This research therefore aimed to evaluate the effectiveness and cost-effectiveness of a combined universal school and parental alcohol intervention called the Steps Towards Alcohol Misuse Prevention Programme (STAMPP).

Objectives

The primary objectives of the research were to:

1. ascertain the effectiveness and cost-effectiveness of a combined classroom and parental intervention (STAMPP) in reducing alcohol consumption (defined as self-reported consumption of ≥ 6 units for male students and ≥ 4.5 units for female students in a single episode in the previous 30 days) in school pupils [in school year 9 in Northern Ireland (NI) or in S2 in Scotland in the academic year 2012–13 and aged 12–13 years] at 33 months after the baseline time point (T3)
2. ascertain the effectiveness of STAMPP in reducing alcohol-related harms, as measured by the number of self-reported harms (harms caused by own drinking such as getting into fights after drinking, poorer school performance and trouble with friends and family), in school pupils (school year 9 or S2 in the academic year 2012–13 and aged 12–13 years) at T3.

Methods

Study design

The trial was a cluster randomised controlled trial conducted in NI and Glasgow/Inverclyde Education Authority areas in the UK with schools as the unit of randomisation.

Participants

The participants were male and female school students (school year 9 or S2 in the academic year 2012–13 and aged 12–13 years) attending mainstream secondary schools in NI and Glasgow/Inverclyde. In each participating school, all students in attendance at the time of data collection were asked to complete the project questionnaires.

Interventions

The Steps Towards Alcohol Misuse Prevention Programme combined a school-based alcohol harm reduction curriculum and a brief parental intervention that was designed to support parents/carers in setting family rules around drinking. The programme rationale was that stricter parental/carer rules and attitudes towards alcohol would reinforce learning and skills development in the classroom. The classroom component was the School Health and Alcohol Harm Reduction Project (SHAHRP) [McBride N, Farrington F, Midford R, Meuleners L, Phillips M. Harm minimization in school drug education: final results of the School Health and Alcohol Harm Reduction Project (SHAHRP). *Addiction* 2004;**99**:278–91], which combined a harm reduction philosophy with skills training, education and activities designed to encourage positive

behavioural change. It was a curriculum-based programme that was delivered in two phases over a 2-year period. The intervention was interactive, and was developmentally and experientially relevant to recipients' drinking trajectories. It was adapted from an original Australian programme in an early study with the assistance of education and prevention specialists. The brief intervention delivered to intervention pupils' parent(s)/carer(s) comprised a short, standardised presentation delivered by a trained facilitator (independent of the trial team) at specially arranged evenings on school premises. The presentation included an overview of the Chief Medical Officer's 2009 guidelines for drinking in childhood (Donaldson L. *Guidance on the Consumption of Alcohol by Children and Young People*. London: Department of Health; 2009), information on alcohol prevalence in young people, corrected (under)estimates of youth drinking rates and highlighted the importance of setting strict family rules around alcohol. The presentation was followed by a brief discussion on setting and implementing authoritative family rules on alcohol. All intervention pupils' parents/carers were followed up by a mailed leaflet, whether or not they attended the parents' evening, which provided a summary of the key information delivered in the evening and coincided with phase 2 of the classroom intervention.

Sample size

The study was powered to detect a standardised effect size of $\delta = 0.2$, or a 10% absolute reduction in risk (51% vs. 41%), for the primary outcome of heavy episodic drinking (HED) (80%; $\alpha = 0.05$; intracluster correlation coefficient 0.09). Assuming 20% attrition within each cluster (from 100 to 80 pupils), the target sample size was 90 schools and 9000 students at baseline.

Randomisation

Following recruitment, schools ($n = 105$) were randomised to the intervention (schools, $n = 52$; pupils, $n = 6379$) or the control (schools, $n = 53$; pupils, $n = 6359$) condition. Baseline data were collected when pupils were in school year 8 or S1. Schools were stratified by school type (all-boys' school/all-girls' school/coeducation school) and socioeconomic status (SES) [using the percentage of pupils entitled to free school meals (FSMs), categorised as a tertile split: low, moderate or high].

Stratified randomisation was used to balance the arms and was performed separately for Glasgow/Inverclyde and NI. Schools in Glasgow/Inverclyde were stratified based on FSM provision. As more schools were recruited in NI, two stratification factors were identified: FSM provision and school type.

Outcome measures

The primary outcomes were (1) self-reported alcohol use (HED, defined as the self-reported number of occasions in the previous 30 days on which male students consumed ≥ 6 units of alcohol or female students consumed ≥ 4.5 units in a single episode), which was dichotomised at never and one or more occasion; and (2) the number of self-reported harms (harms caused by own drinking). The primary economic effectiveness measures were in line with the primary outcome measures. The primary outcomes were assessed at T3 using a self-completed questionnaire.

Secondary outcomes were also self-reported, and included the primary outcomes assessed at 12 months after the baseline time point (T1) and 24 months after the baseline time point (T2): self-reported alcohol use (lifetime, previous year and previous month) was assessed at T1, T2 and T3; support service utilisation was assessed at T2 and T3; the number of self-reported harms caused by the drinking of others was assessed at T1, T2 and T3; age at alcohol initiation was assessed at T1, T2 and T3; unsupervised alcohol use was assessed at T1, T2 and T3; and the number of units of alcohol consumed in a 'typical' episode and the last-use episode were assessed at T1, T2 and T3.

Analysis

Primary and secondary analyses were performed using the complete case (CC) population. The health economic analysis was also conducted on the CC population. For each primary outcome, a two-level regression model was fitted, with pupils nested within schools, to assess the impact of STAMPP on the

outcome measures. For self-reported consumption of $\geq 6/\geq 4.5$ units, the model used was logistic regression. For the number of self-reported harms, a negative binomial model was used.

The primary outcome model was adjusted for the impact of covariates on intervention outcome. Covariates included in the models were those used within the randomisation process (sex and SES), baseline outcome measures (consumption of $\geq 6/\geq 4.5$ units and number of self-reported harms depending on outcome) and location (NI and Glasgow/Inverclyde). For each primary outcome, a statistically significant result was concluded if the *p*-value for the trial arm explanatory variable was < 0.025 .

Preplanned subgroup analyses on primary and secondary outcome measures were conducted, and prespecified interaction terms were fitted between trial arm and baseline measures thought to predict the effect of treatment. These were age, sex, SES, alcohol use at baseline and, in NI, a grammar/secondary school analysis.

Sensitivity analyses included repetition of the analysis on alternative specifications of outcome measures, using the intention-to-treat population and different missing data models.

The cost-effectiveness of STAMPP was estimated using conventional decision rules and reported as incremental cost-effectiveness ratios (ICERs) when appropriate. Uncertainty in the cost-effectiveness measures was investigated by bootstrapping multilevel models relating to public service costs and outcomes, and using the incremental costs and outcomes to generate 1000 replications of the ICERs. The resulting replicates were plotted on the cost-effectiveness plane and used to construct cost-effectiveness acceptability curves. Construction of these curves involved a series of lines being placed on the plane representing different willingness-to-pay thresholds.

Process outcomes were assessed across eight prespecified domains using nine data sources. Assessments included focus groups with pupils, an online survey with teachers and interviews with senior school staff and stakeholders. Fidelity and completeness of delivery were assessed using bespoke tools and calculation of participation rates at the parent/carer evening.

Analyses were conducted using *Mplus* version 7.11 (Muthén & Muthén, Los Angeles, CA, USA) for multivariate regression models and *Stata/IC* version 12.0 (StataCorp LP, College Station, TX, USA) for the health economic analysis. NVivo version 10 (QSR International, Warrington, UK) was used for the qualitative analysis.

Results

Study population

Overall retention was high. Of the full sample [those who completed a questionnaire at either the baseline time point (T0) or T1; $N = 12,738$], 10,405 also completed the questionnaire at T3 (81.7%). For the HED outcome, data were available for 5160 intervention and 5073 control pupils. For the harms outcome, data were available for 5234 and 5146 pupils, respectively. No schools withdrew from the trial and no pupils or parents/carers withdrew consent.

Trial results

The prevalence of HED was 9 percentage points higher in the control group (26%) than in the intervention group (17%) at T3. This represented a significant intervention effect [estimate -0.516 , standard error (SE) 0.102; $p < 0.001$]. The odds ratio (OR) for the intervention effect was 0.596 (SE 0.0596). The corresponding 95% confidence interval (CI) for the OR ranged from 0.490 to 0.725.

Around two-thirds of the pupils (63%) reported no alcohol-related harms at T3 (60.7% control; 65.1% intervention). The median number of harms was equivalent in each study arm (0), although the interquartile range was smaller in the intervention arm than in the control arm (2 and 3, respectively).

The negative binomial model used showed that the intervention arm was not a significant predictor of harms (estimate -0.101 , SE 0.083 ; $p = 0.222$; incident rate ratio 0.916 , 95% CI 0.780 to 1.052). Similar covariates (sex, SES, baseline outcome and location) were included in both the harms and HED outcome models.

Therefore, the intervention was effective in reducing HED, but not harms resulting from own drinking.

Examining secondary outcomes, no parameter estimates were significant for the intervention arm, indicating no effects of intervention. Similarly, no significant interactions were identified in the prespecified subgroup analyses.

Process evaluation results

Clusters were successfully recruited into STAMPP, randomisation was successful and schools were comparable across intervention arms at baseline. No adverse events were reported.

The content of the classroom component of STAMPP was delivered largely as intended, although the number of lessons it was delivered over was slightly higher than intended (mean of 8.1 ± 2.61 lessons in phase 1 when it should have been delivered in 6; and 6.65 ± 3.0 and 4, respectively, in phase 2). The curriculum was delivered in most schools as part of their personal, social, health and economic education (or local equivalent) curriculum and did not replace statutory activities. It was enjoyed by pupils, who reported that they found it interesting, informative and relevant to their own experiences. This contrasted with the largely negative perceptions of alcohol education reported by pupils in the education as normal (EAN) condition. Teachers' evaluation of the classroom component was also positive, and it was viewed as complementing the schools' wider health and well-being strategies. Teachers and school management believed that it was possible to accommodate the programme in the curriculum, that the supporting resources were useful and that the content was both age and experientially appropriate. In contrast, there was very low uptake of the parental/carer component. It should, therefore, be concluded that this component was not successfully implemented.

Economic evaluation results

The Steps Towards Alcohol Misuse Prevention Programme was found to be a relatively low-cost intervention (£818 per school and £15 per pupil). The primary cost-effectiveness analysis indicated that, if decision-makers were willing to pay £15 per pupil, the probability that STAMPP was cost-effective would be 56% at T3 and 35% at T2. The levels of uncertainty reflect the considerable variability in the cost differences between groups. As expected by the lack of intervention effect on alcohol-related harms, STAMPP did not bring about clear public sector cost savings; however, neither did it increase them or lead to any cost shifting within the public sector categories. STAMPP can, therefore, be considered to weakly dominate EAN because it was both cost neutral and more effective.

Conclusions

The results of this trial provide some support for the effectiveness and cost-effectiveness of a combined and adapted the SHAHRP and brief parental intervention for reducing HED, but not for reducing alcohol-related harms, in young people over a 33-month follow-up period. One possible interpretation of these findings is that reducing HED without impacting the self-reported harms assessed in this study is not a desirable outcome for either a prevention or a harm reduction programme. The harms assessed in the study might not have been age-appropriate, and it is also plausible that effects on harms would manifest later; further research would clarify these possibilities. As there was low uptake of the parental component, it is uncertain whether or not the intervention effect was accounted for by the classroom component alone.

Implications for practice

The Steps Towards Alcohol Misuse Prevention Programme was shown to be more effective than EAN at reducing HED and was cost neutral. Harms from alcohol consumption were not impacted by STAMPP. The programme may therefore form part of comprehensive local alcohol strategies where reductions in HED are a primary consideration. However, although the classroom component was enjoyed by pupils and valued by teachers and senior school staff, the parental/carer component failed to attract parents, and it may also be difficult in practice to engage this target group.

Recommendations for research

Further work is required to understand whether or not STAMPP had differential effects on subgroups defined by alcohol risk and context of use (e.g. growth trajectories in baseline supervised users vs. baseline unsupervised users), if effects on HED are maintained at extended follow-up points (as the intervention appeared to be more effective at T3 than at T2) and if effects on harms begin to emerge as drinking naturally becomes more regular in later adolescence. If the finding on HED is robust, mediation analysis should be used to better understand how the intervention works. In order to better interpret the effects of the intervention, it would also be useful to examine whether or not changes in drinking are also associated with educational attainment and with health and social outcomes. For example, matching STAMPP data with examination performance or with service monitoring data (e.g. hospital presentations, criminal justice data) may be useful in this regard. Finally, if funders and other decision-makers decide to support STAMPP in the future on the basis of the findings of this research, then it is important that implementation outside the structure of the trial is investigated. For example, it is important to understand how programme impact is affected if modifications are made to intervention content and delivery. Similarly, the delivery of STAMPP by alternative providers (e.g. youth workers, non-governmental organisations) may also have implications for programme effectiveness. Finally, interventions and curricula such as STAMPP are delivered within an environment of alcohol marketing (as opposed to the being delivered in isolation), and so there is a need to better understand how different intervention approaches and actions (e.g. licensing, marketing restrictions, whole-school policies) interact with one another and how interventions can be optimised within complex health systems. The use of systems mapping exercises and the study of alcohol prevention as a complex system may be one means to maximise the effects of combinations of different prevention types.

Trial registration

This trial is registered as ISRCTN47028486.

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