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

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 Manuscripts

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3 **1 Steps towards alcohol misuse prevention programme (STAMPP): a school and**
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5 **2 community based cluster randomised controlled trial**
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2
3 **26 Abstract** (Word count: 300)
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6 **27 Objectives:** To assess the effectiveness of a combined classroom curriculum and
7
8 **28 parental intervention** (The Steps Towards Alcohol Misuse Prevention Programme;
9
10 **29 STAMPP)**, compared to alcohol education as normal (EAN), in reducing self-reported
11
12 **30 heavy episodic drinking (HED) and alcohol-related harms (ARH) in school children.**
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15 **31**
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17 **32 Setting:** 105 High schools in Northern Ireland (NI) and in Scotland.
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19

20 **33**
21 **34 Participants:** Schools were stratified by free school meal provision. Schools in NI
22
23 **35 were also stratified by school type (male/female/co-educational). Eligible students**
24
25 **36 were in school year 8/S1 (aged 11-12) at baseline in June 2012.**
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27

28 **37**
29
30 **38 Intervention:** A classroom-based alcohol education intervention, coupled with a brief
31
32 **39 alcohol intervention for parents/carers.**
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35 **40**
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37 **41 Primary Outcomes:** The study had two primary outcomes at +33 months; the
38
39 **42 prevalence of self-reported HED in the previous 30 days and the number of self-**
40
41 **43 reported ARHs in the previous six months.**
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44 **44**
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46 **45 Results:** At 33 months data were available for 5,160 intervention and 5,073 control
47
48 **46 students (HED outcome), and 5,234 and 5,146 students (ARH outcome) respectively.**

49 **47 Of the full sample (those who completed a questionnaire at either baseline or 12**
50
51 **48 months, N=12,738), 10,405 also completed the questionnaire at 33 months (81.7%).**

52 **49 Fewer students in the STAMPP group reported HED compared to EAN (17% versus**
53
54 **50 26%; odds ratio=0.60, 95% CI 0.49-0.73). There was no difference in the number of**
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3 51 self-reported ARHs (incident rate ratio = 0.92, CI 0.78-1.05). Although the classroom
4
5 52 component was largely delivered as intended, there was low uptake of the parental
6
7 53 component. There were no reported adverse effects.
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11 55 Conclusions: Results suggest that STAMPP could be an effective school-based
12
13 56 program to reduce the prevalence of HED in young people. Whilst we did not find a
14
15 57 reduction in ARH, it is plausible that effects on harms would manifest later.
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20 59 Trial Registration: The trial was registered, number ISRCTN47028486
21
22 60 (<http://www.isrctn.com/ISRCTN47028486>). The date of trial registration was
23
24 61 23/09/2011, and school recruitment began 01/11/2011.
25
26 62

27 63

30 64 Article Summary

31 65 Strengths and Limitations.

- 32 66 • All data are longitudinal;
- 33 67 • The sample size was very large and attrition relatively low;
- 34 68 • Participants were independently randomised;
- 35 69 • Some of those involved in fieldwork were not blind to participant condition;
- 36 70 • Overall levels of alcohol-related harm were low.

37 71
38 72 Keywords: alcohol; prevention; school based intervention; alcohol related harm;
39 73 universal prevention; adolescents
40 74
41 75

76 **Introduction**

77 Adolescence is a period when young people experiment with alcohol, and as they age
78 the amount and frequency of consumption increases.(1) Research has shown that
79 family socialisation factors such as approval of adolescent drinking and the provision
80 of alcohol in the home predicts drinking among adolescents and young adults (2-4)
81 An earlier onset of self-reported drunkenness and the establishment of regular alcohol
82 drinking is associated with a greater risk of adult alcohol-related problems.(5) There
83 are also clear geographic and socioeconomic differences in the burden alcohol places
84 on the population, and these are closely associated with other major indicators of ill
85 health and health inequalities. (6-8)

86
87 Previous literature reviews have highlighted a lack of high quality trials of
88 universal school-based universal alcohol prevention programmes, and few approaches
89 studied have shown positive intervention effects.(9-15) However, while reviews have
90 been unable to recommend any single prevention initiative, many have concluded that
91 interventions that develop social skills appear to be superior to those that seek to
92 enhance only knowledge.(10-13) Guidance issued by the National Institute for Health
93 and Care Excellence (NICE) in the UK in 2007 called for partnerships between
94 schools and other stakeholders in efforts to prevent misuse.(16) Reviews of universal
95 alcohol prevention in family settings suggest that activities supporting parenting
96 skills, including establishing clear boundaries or rules and parental monitoring, may
97 be effective.(9, 17, 18) Primary studies also suggest that when combined with a
98 school-based alcohol curriculum, provision of advice to parents about setting strict
99 rules around alcohol consumption reduces adolescent drinking.(19, 20)

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3 100 The Steps Towards Alcohol Misuse Prevention Programme (STAMPP)
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5 101 intervention combined a culturally adapted intervention based on the School Health
6
7 102 and Alcohol Harm Reduction Project (SHARHP)(21) curriculum with a researcher-
8
9 103 developed brief parental intervention based on the Swedish Örebro Prevention
10
11 104 Program.(22) SHAHRP is an example of a resistance skills training programme, and
12
13 105 includes elements of alcohol-specific personal and social skills training. (23-26) In
14
15 106 accordance with the theoretical assumptions underlying such programmes, it includes
16
17 107 three main strategies : (i) teaching students to recognise high-risk situations, (ii)
18
19 108 increasing the awareness of external influences on behaviour, and (iii) combining self-
20
21 109 control (i.e. the ability to control responses, to interrupt undesired behavioural
22
23 110 tendencies and refrain from acting upon them) with refusal skills training (i.e. in order
24
25 111 to improve self-efficacy in avoiding unhealthy behaviours, but not with the
26
27 112 consequence of social disadvantage for the young person with their peers). The
28
29 113 knowledge delivered through SHAHRP (e.g. lessons on effects of alcohol, description
30
31 114 of alcohol units) was not assumed to have direct preventative effects, but instead
32
33 115 hypothesised to shape and alcohol attitudes and support situation-specific decision
34
35 116 making. The parental component was based on research indicating that restrictive
36
37 117 parenting practices (e.g., monitoring of children's alcohol use, healthy attitudes
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39 118 towards alcohol, alcohol rule-setting) was associated with reduced prevalence of
40
41 119 children's alcohol use (20). When this approach was delivered alongside a classroom
42
43 120 intervention in the Dutch PAS, programme effect was mediated through children's
44
45 121 perceptions of parental rules, child self-efficacy, and child self-control. (27)
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52 123 It was hypothesised that fewer students in schools delivering STAMPP would
53
54 124 self-report: (i) past 30-day heavy episodic drinking (HED) at final follow-up (33

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3 125 months from baseline); and (ii) fewer self-reported alcohol-related harms (ARH) at
4
5 126 final follow-up than those in schools delivering alcohol education as normal (EAN).
6
7 127 These primary aims of the research trial were to assess whether STAMPP was
8
9 128 effective in reducing self-reporting of these two indicators of alcohol use.
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130 **Materials and Methods**

131 **Study design**

132 This was a cluster randomised controlled trial (cRCT) of school children in Northern
133 Ireland (NI) and Glasgow/Inverclyde Education Authority (Scotland) areas in the
134 United Kingdom (UK) with schools as the unit of randomisation. The research was
135 approved by Liverpool John Moores University Research Ethics Committee
136 (11/HEA/097). The trial protocol is available from
137 <http://www.nets.nihr.ac.uk/projects/phr/10300209>.

138

139 **Participants**

140 The sampling frame comprised all mainstream post primary schools in NI (excluding
141 those within the Eastern Health Board due to existing delivery of SHAHRP in that
142 area) and in Glasgow/Inverclyde Local Authorities. All schools in the sampling frame
143 were assessed for satisfaction of the inclusion criteria and willingness to participate in
144 the trial.

145 A total of 105 schools were invited to participate in the trial, and all accepted;
146 70 in NI, 30 in Glasgow Local Authority and five in Inverclyde Local Authority.
147 Inclusion criteria were schools in NI and Scotland that taught students in school year
148 8/S1 in the academic year 2011/2012 (aged 11/12 at randomisation). Exclusion

1
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3 149 criteria were schools that did not include students in the specified school year, or only
4
5 150 provided non-mainstream or vocational education (e.g. pupil referral units, further
6
7 151 education colleges). Individual students with special educational needs in mainstream
8
9 152 classrooms were excluded at the discretion of teachers as the intervention materials
10
11 153 had not been developed for use with this population.
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16 155 Participants were eligible students in the randomised schools, who consented
17
18 156 to participate. Opt in consent was obtained from school head-teachers/principals
19
20 157 before randomisation. Opt out consent from participants and their parents/guardians
21
22 158 was obtained after randomisation. No schools withdrew from the trial and no pupils or
23
24 159 parents/carers withdrew consent. Data was collected under examination-like
25
26 160 conditions on school premises.
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30 31 162 **Randomisation and blinding**

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34 163 Schools were randomly assigned (1:1) to receive STAMPP or alcohol EAN before
35
36 164 baseline data were collected. Randomisation was performed by an independent
37
38 165 statistician blind to the identity of the schools. All schools were stratified on Free
39
40 166 School Meal Provision (FSM; low/moderate/high), which was taken as a proxy for
41
42 167 socio-economic status. Schools in NI were also stratified by school-type
43
44 168 (male/female/co-educational).
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49 170 Schools, students, intervention trainers and delivery staff (teachers) were not
50
51 171 blind to study condition. Data collection was undertaken by a team of researchers that
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53 172 included the trial manager and research assistants, some of whom were not blind to
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55 173 study condition.
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4
5 175 Data analysis of primary and secondary outcomes was undertaken by the trial
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7 176 statistician who was blinded to the study condition.
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10 11 178 **Procedures**

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14 179 STAMPP combined a school-based skills development curriculum, and a brief
15
16 180 parental intervention designed to support parents in setting family rules around
17
18 181 drinking (see Table 1 for overview of the intervention). The classroom component of
19
20 182 STAMPP was based on the SHAHRP intervention and culturally adapted for the
21
22 183 settings of delivery.(28) It combined skills training, education, and activities designed
23
24 184 to encourage positive behavioural change.(21) It was a curriculum-based programme
25
26 185 delivered in two phases over a two year period. As part of the trial, the first phase was
27
28 186 delivered when students were in school year 9/S2 (age 12-13 years) and the second
29
30 187 phase was delivered during the subsequent year.
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36 189 The parental component of STAMPP was developed by the trial team and was
37
38 190 based on the programme structure of Koutakis and colleagues (22), and Koning and
39
40 191 colleagues. (19, 20) The component differed in two main ways to these earlier
41
42 192 programmes. Firstly, as part of STAMPP, delivery of a single parental component
43
44 193 coincided with the delivery of phase two of the classroom curriculum, whereas in
45
46 194 Koutakis and Koning, parents' evenings were held several times over the intervention
47
48 195 delivery phase. Secondly, the session was partly based upon guidelines included in the
49
50 196 UK Chief Medical Officers' 2009 guidelines for drinking in childhood (29). All
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52 197 intervention pupil parents, regardless of whether they had attended the evening or not,
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198 were mailed an information leaflet a few weeks after the parental session which
199 reinforced the discussion points.

For peer review only

200 **Table 1.** Stages in the STAMPP Trial

201

| Stage | Description |
|------------------------|--|
| Recruitment of schools | <ul style="list-style-type: none"> • Schools in Glasgow Local Authority (n = 30) were recruited as a complete group following negotiations with Education Services • Schools in Inverclyde (n = 5) were recruited following a meeting with the Headteachers/Principals to discuss the practicalities of the trial. • Schools in Northern Ireland (n = 70) were recruited individually in the following process: letter of information; follow-up telephone call; individual meeting with Headteacher/ Principals; agree yes/no. |
| Training of teachers | <ul style="list-style-type: none"> • One-day training events were held in each study site before both phases of delivery of the classroom component. Training for the following academic year (from September onwards) took place in the preceding June. • Training involved lectures on alcohol (e.g. effects of alcohol use; prevalence rates; risk and protective factors for alcohol use), sharing experiences on previous delivery of the programme, and skills rehearsal for each of the SHAHRP lessons. • Training involved examination of each of the SHAHRP Lessons which covered: Myths about Alcohol; Units of Alcohol; Reasons why people do/don't drink; Alcohol and the Body; Consequences of 'levels' of drinking; Blood Alcohol Concentration; Social and Personal Harms; Alcohol Policy; Alcohol and the Media; Advice for Teenagers; A 'Night Out'; Pressures faced by Young Drinkers; Scenario-based discussion. • Each lesson was scheduled to last one lesson period (approximately 40 minutes) and delivered once a week |

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| | <ul style="list-style-type: none"> Teachers were provided with support materials (CD-ROMS, workbooks) at each training session to help implement the lessons. |
| Intervention Period | <ul style="list-style-type: none"> The intervention period was September to November in both academic years. Phase One involved six lessons and Phase Two, four lessons. Schools were asked to complete all lessons within the three-month delivery window in both phases. The Parental Brief Intervention coincided with delivery of Phase Two when the children were in their third year of secondary school and took place in the evening on Intervention school premises The intervention included a brief presentation on the UK Chief Medical Officers’ guidelines on alcohol use by young people, and a discussion on setting family rules on alcohol. All Intervention student parents, regardless of whether they had attended the evening or not, were mailed a leaflet which reinforced these points a few weeks after the parental session Final data collection for the primary outcome took place one year after all elements of the intervention had been delivered. |

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3 The control group participants continued with alcohol EAN within their
4 school, which included standard personal, social, and health education, but would not
5 be uniform across all such schools. Parents/carers of control students did not receive
6 the STAMPP intervention or materials, but may have been exposed to alcohol
7 intervention activities in the community as part of independent provision.
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16 Questionnaires were administered to participants at baseline in June 2012 and
17 at three follow-ups: 12, 24, and 33 months. All students that were present at baseline
18 or joined participating schools prior to delivery of Phase 1 of the intervention were
19 included in the analyses. Parents/carers were asked to complete a short postal
20 questionnaire, which coincided with delivery of the information leaflet. Alcohol rules
21 were assessed using a 10-item scale to measuring the degree to which parents/carers
22 permitted their children to consume alcohol in various situations, such as 'in the
23 absence of parents at home' or 'at a friend's party' ($\alpha = 0.86-0.90$). (30) Parental
24 alcohol self-efficacy was assessed using a three item scale assessing the level of
25 confidence the parent/carer had in their own ability to prevent their child from
26 drinking ($\alpha = 0.67$). (31) This data was collected to inform future mediation analysis
27 and is not reported here.
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44 **Outcomes**

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46 The study had two primary outcomes at 33 months; (i) the prevalence of self-reported
47 HED drinking in the previous 30 days (HED defined as the consumption of ≥ 6 units
48 [males]/ ≥ 4.5 units [females] on one or more occasions) and (ii) the number of self-
49 reported harms (caused by own drinking) in the previous six months in students. Pre-
50 specified secondary outcomes are described in the online supplementary material,
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3 except for those related to the cost-effectiveness analysis which will be reported
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5 elsewhere. The original primary outcome was self-reported frequency of consumption
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7 of >5 'drinks' in a single drinking episode. However, concerns arose because it
8
9 became clear that '>5 drinks' could refer to drinks of different alcohol strength and
10
11 volume. As the objective of the intervention was to reduce HED, the primary outcome
12
13 was changed to consumption of ≥ 6 units for males, and ≥ 4.5 units for females – both
14
15 are 1.5 times the Chief Medical Officer's maximum daily guideline for adults,(29)
16
17 and this was ratified by the independent Study Steering Committee. This change was
18
19 implemented before the final wave of data collection, before unblinding, and before
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21 any analysis of trial outcome measures at any data collection point had been
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23 undertaken.
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29 To assess the HED primary outcome, participants were presented with pictorial
30
31 prompts of how much alcohol $\geq 6/\geq 4.5$ UK units represents. Pictures presented the
32
33 most popular drinks consumed in the two study areas and respondents were asked to
34
35 report the frequency of consuming this amount of alcohol over the previous month.
36
37 Harms associated with own use of alcohol were measured using a 16-item scale
38
39 developed for the Australian SHAHRP trial (internal consistency 0.9). (32)
40
41 Participants were asked to indicate on a Likert scale how many times in the past six
42
43 months they had experienced the individual harm. For example, participants were
44
45 asked to report frequency of having a hangover after drinking, or if they had got into a
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47 physical fight when drinking.
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52 **Statistical analysis**

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3 It was calculated that a sample size of 90 schools (45 per study arm; 80 students per
4 school) would be powerful enough (80%; $\alpha=0.05$; ICC = 0.09 based on data from the
5 Belfast Youth Development Study (33)) to detect a standardised effect size of $\delta = 0.2$,
6
7 or a 10% absolute reduction in risk (51% vs. 41%) for the primary outcome of HED.
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9 Assuming 20% attrition within each cluster (from 100 to 80 students), the target
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11 sample size was 90 schools and 9000 students at baseline.
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18 Summary statistics on school and student recruitment, withdrawal and dropout
19
20 were collated for both trial arms and reported as a participant flow diagram for
21
22 reporting of cRCT (Fig 1). Outcome measure scores from the questionnaires were
23
24 summarised and tabulated for the trial arms.
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29 The outcome analysis was an Intention to Treat (ITT) analysis using the
30
31 Complete Case (CC) population such that all cases were assessed regardless of
32
33 intervention and intervention dosage. Logistic regression models estimated the
34
35 association between STAMPP and the odds of self-reported HED. Negative binomial
36
37 regression models estimated the association between STAMPP and the number of
38
39 AHR. All models included school-level random intercepts to account for correlation
40
41 due to clustering of students within schools. All models adjusted for factors used to
42
43 stratify randomization and the outcome's corresponding value at baseline. For details
44
45 of analysis of secondary outcomes please see the supplementary material.
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50 For each primary outcome, a statistically significant result was concluded if
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52 the *p*-value for the trial arm explanatory variable was <0.025 .
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3 Sensitivity analyses included repetition of the primary outcome analysis using
4 the ITT population with different missing data models. These included a “best case”
5 (missing set to non-HED), “worst” case (missing set to HED), “conservative case”
6 (missing in control arm set to non-HED, missing in intervention arm set to HED) and
7 multiple imputations (with 50 imputed data sets).
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15 To explore differential intervention effects on the primary measures, pre-
16 specified interaction terms were fitted between trial arm and baseline measures
17 thought to predict the effect of intervention on primary outcomes. These were: age
18 (months) at baseline; gender; socioeconomic status (proportion of students in receipt
19 of FSM tertile split); alcohol use behaviour at baseline – age of initiation, use of
20 alcohol in the year prior to baseline, context of use
21 (abstainer/supervised/unsupervised); and in NI, Grammar/Secondary school.
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33 Process outcomes were assessed across eight pre-specified domains (including
34 intervention acceptability and assessment of the content of EAN), using nine data
35 sources. Methodologies included focus groups with students, an online survey with
36 teachers, and interviews with senior school staff and stakeholders. Fidelity and
37 completeness of delivery were assessed using bespoke tools and calculation of
38 participation rates at the parent/carer evening.
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48 Data cleaning, data management and preliminary analysis were undertaken
49 using IBM SPSS version 20+. Mplus 7.11 was used for all analyses and Stata/IC 12.0
50 was used to verify Mplus models and generate odds ratios (OR).
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3 The trial was registered, number ISRCTN47028486.
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7 **Ethics approval and consent to participate**

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10 The research was approved by Liverpool John Moores University Research Ethics
11 Committee (11/HEA/097). Participants were eligible students in the randomised
12 schools, who consented to participate. Consent was obtained from school head-
13 teachers/principals before randomisation. Consent was obtained from participants and
14 their parents/guardians after randomisation. This was through an opt-out method as
15 opt-in written consent was not required by the ethics committee.
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25 **Results**

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28 Fig 1 shows participant flow through the trial. School recruitment began in November
29 2011 and ended in January 2012. As this was a cRCT of an intervention taking place
30 across several years, student numbers refer to those who completed the questionnaire
31 at each data collection period. No participant or parent/carer requested data
32 retrospectively removed from analysis. Multiple data collection 'mop up' visits were
33 undertaken with schools, therefore attrition represents students who were absent on
34 data collection days rather than formal drop out. Of the full sample (those who
35 completed a questionnaire at either baseline or 12 months, N=12,738), 10,405 also
36 completed the questionnaire at 33 months (81.7%). There was a higher attrition rate
37 amongst students who were male (19.0%), in receipt of FSM (25.8%), and had used
38 alcohol at baseline (25.4%). There was little difference in attrition between the control
39 and intervention arms of the trial (around one percentage point difference). Attrition
40 also varied by location, with a higher rate in Scotland (24.0%) compared to NI
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3 (15.0%). Across schools attrition varied from 1.5% to 32.0%. There were no
4
5 unintended harms or adverse effects reported.
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7 **INSERT FIG 1 HERE**

8
9 **Fig 1. School and participant flow diagram - STAMPP Trial.** Analysis was
10 conducted at 33 months on students who had completed each of the primary outcome
11 measures. N = number of schools; n = student numbers
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19 Baseline data collection took place in June 2012 with the following follow up
20 data collection points: 12 months (after delivery of phase one of the classroom
21 component); 24 months (after delivery of the parental intervention and phase two of
22 the classroom component); and 33 months. The trial ended as planned after final data
23 collection and analysis.
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31 Baseline characteristics of students (n=11,316) are presented in Table 2.
32
33 Overall parental/carer participation was low. A total of 319 parent(s)/carer(s) attended
34 the intervention evenings in NI (9% of those eligible) and 63 parents attended in
35 Scotland (2.5%). With respect to the follow-up mailed intervention, 1074 returns were
36 received from parent(s)/carer(s) in NI (a 31% return) and 440 in Scotland (18%).
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44 **INSERT TABLE 2 HERE**

Table 2. Baseline characteristics of students according to study condition.

| | Control | Intervention |
|--------------------------|-------------------------|-------------------------|
| | n (% _{valid}) | n (% _{valid}) |
| Total (n=11,316) | 5567 (49.2) | 5749 (50.8) |
| <i>Gender</i> | | |
| Male | 2787 (51.1) | 2834 (50.0) |
| Female | 2670 (48.9) | 2829 (50.0) |
| Missing | 110 | 86 |
| <i>Free School Meals</i> | | |
| No | 4289 (77.3) | 4436 (77.5) |
| Yes | 1258 (22.7) | 1290 (22.5) |
| Missing | 20 | 23 |
| <i>Location</i> | | |
| NI | 3469 (62.3) | 3554 (61.8) |
| Scotland | 2098 (37.7) | 2198 (38.2) |
| Missing | 0 | 0 |
| <i>HED^a</i> | | |
| No | 5082 (92.2) | 5261 (92.4) |
| Yes | 432 (7.8) | 431 (7.6) |
| Missing | 53 | 57 |
| <i>Ethnicity</i> | | |
| White | 4492 (95.3) | 4495 (94.5) |
| Non-white | 248 (4.5) | 293 (5.5) |

Missing 827 961

Note: The percentages are calculated on the basis of the complete cases only.

^a Assessed at baseline as consuming > 5 drinks in one or more episodes in the last 30 days.

Table 3 shows the count and percentages of respondents reporting drinking above the primary outcome threshold ($\geq 6/\geq 4.5$ units) at 33 months, and the adjusted model results by study arm (OR; Incidence rate ratio, IRR). Around one in 5 participants reported at least one episode in the last 30 days. The prevalence of episodes was around nine percentage points higher in the control group (26%) than in the intervention group (17%). Taking the within (pupil) level variance (fixed at 3.29) and the between (school) level variance (0.454 for the full sample), estimated using a null two level model, the corresponding ICC for the full sample was 0.121. Supplementary Table S1 shows the full random intercept models for the primary outcomes at 33 months.

Table 3 Primary outcomes at 33 months by study group

| | Unadjusted results | | Adjusted model results | |
|----------------------|-------------------------|-------------------------|------------------------|-----------|
| | Control | Intervention | OR/IRR | 95% CI |
| | N (% _{valid}) | N (% _{valid}) | | |
| HED (frequency) | | | | |
| None | 3773 (74.4) | 4281 (83.0) | 0.60 | 0.49-0.73 |
| One or more occasion | 1300 (25.6) | 879 (17.0) | | |
| <i>Missing</i> | <i>1286</i> | <i>1219</i> | | |
| ARH (frequency) | | | | |

| | | | | |
|----------------------|-------------|-------------|------|-----------|
| None | 3126 (60.7) | 3408 (65.1) | 0.92 | 0.78-1.05 |
| One or more occasion | 2020 (39.3) | 1826 (34.9) | | |
| <i>Missing</i> | <i>1213</i> | <i>1145</i> | | |
| Median (IQR) | 0 (2) | 0 (3) | | |

OR, odds ratio; IRR, incidence rate ratio; *HED*, Heavy episodic drinking; ARH, Alcohol related harms

Fig 2 displays the count of respondents reporting ARH at 33 months by study group. Around two thirds of students (63%) reported no alcohol-related harms. The median number of harms was equivalent in each study arm (0), while the interquartile range was smaller in the intervention arm than in the control arm (2 and 3 respectively).

INSERT FIG 2 HERE

Fig 2. Count of school children reporting one or more alcohol related harms by study arm

At the school level, the parameter estimates were significant for the intervention arm (estimate = -0.516, SE=0.102; $p < 0.001$). Schools in the intervention arm had lower levels of HED (their intercepts) than those in the control arm (OR = 0.596, 95% CI 0.490 – 0.725). This represents a significant intervention effect. However, with respect to ARH, the intervention indicator was non-significant suggesting no difference between the intervention and control schools (estimate = 0.101, SE = 0.083; $p = 0.222$; IRR = 0.916, 95% CI 0.780 – 1.052). Identical models were also estimated on the imputed data sets, yielding similar results. For the sensitivity analysis models the intervention arm coefficient remained significant and

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3 retained the same sign (i.e. being a school in the intervention arm was associated with
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5 having a lower intercept), except for the conservative case model.
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10 There were no significant intervention effects observed for primary outcomes
11 assessed at +24 months (Supplementary Table S2); and secondary outcomes assessed
12 at +33 months (Supplementary Table S3) and + 24 months (Supplementary Table S4).
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14 Given the high correlation between ever use, last year use and the two primary
15
16 outcomes assessed at baseline (Supplementary Table S5), subgroup models were
17
18 estimated on a base of just baseline drinkers (ever and last year use). Whilst the
19
20 intervention was associated with a significant reduction in the number of self-reported
21
22 harms amongst baseline drinkers, it did not reduce self-reported harms amongst the
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24 non-drinkers at baseline (Supplementary Table S6).
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31 **Discussion**

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36 In a large cRCT we found that the STAMPP intervention reduced self-
37 reported HED in the past 30 days at 33 months follow-up from baseline, compared
38 with EAN, but not ARH associated with own drinking. There were no clear or
39
40 consistent effects identified in planned secondary or sub-group analyses (age, gender,
41
42 SES, alcohol use at baseline, location [Scotland vs NI]). It is possible that longer-term
43
44 follow-up and/or emphasis on those drinking might reveal such effects, especially
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46 with regard to self-reported ARH, which were low in both control and intervention
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48 students. The intervention was well received by both pupils and teachers.
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3 Key strengths of the trial were the large sample size (schools and students), low rates
4 of attrition (no schools dropped out), and relatively high rates of matched data (>80%)
5 across survey waves. This means that the analyses were sufficiently powered. There
6 also appeared to be no comparator bias, as monitoring of delivery of EAN in
7 intervention schools showed that this did not include alcohol education. A major
8 limitation of the work was the failure to attract parents/carers to the brief intervention
9 evening, despite the support of many of the schools. Although all intervention
10 students received a mailed follow up leaflet that reinforced the main messages of the
11 parental intervention, relatively low rates of return of the parental questionnaire
12 suggest that only a minority may have read the mailed information. In contrast,
13 parental participation in the structurally similar (i.e. classroom and parental
14 components) Swedish Örebro Prevention Program, and the Dutch Prevention of
15 Alcohol use in Students (PAS) alcohol prevention programmes were relatively high.
16 (20, 22, 34) Universal interventions such as STAMPP require a range of recruitment
17 strategies as there will be different barriers to, and facilitators of, attendance in
18 parental/carer-based actions. Research is therefore needed to assess the relative
19 efficacy of recruitment strategies such as incentives, mass media campaigns, the
20 removal of barriers to attendance (e.g. providing transport and childcare), and the use
21 of key community recruiters (influential individuals and organisations). (35)
22 Furthermore, it is also important to understand if some parent/carer subgroups (e.g.
23 differentiated on child drinking risk) are more likely to respond to particular
24 recruitment strategies, and if this will lead to recruitment biases.
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52 Although we conducted an ITT analysis which helped to preserve sample size, the
53 achieved participation rates are likely to reflect parental/carer attendance in routine
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3 UK practice.(36-38) This meant that we were unable to draw any confident inferences
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5 about the combined impact of the school and parental intervention (*cf* (27)), or the
6
7 relative contribution of each component. In practical terms, this means that although
8
9 the analysis presumed delivery of the combined intervention, discussions with
10
11 stakeholders about research findings and future delivery are likely to focus on the
12
13 classroom component (i.e. culturally adapted SHAHRP). However, it is noteworthy
14
15 that in the PAS programme (20), the classroom component alone did not produce
16
17 changes in alcohol use behaviours, and these were only observed in pupils receiving
18
19 the combined intervention. Subsequent mediation analysis of trial data suggested that
20
21 reduced rate of frequency of drinking or weekly drinking, was mediated by changes in
22
23 parental rules and attitudes towards alcohol (i.e. more strict rules and attitudes were
24
25 developed). It is therefore important that similar analyses are undertaken to better
26
27 understand mediators of behaviour change in STAMPP recipients. Other weaknesses
28
29 of the study included the lack of blinding in intervention delivery and in some data
30
31 collectors. It is plausible that lack of blinding in delivery may led to either under- or
32
33 over-reporting of alcohol use due to social desirability biases, but using an EAN
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35 comparator meant that it was not possible to conceal intervention allocation from
36
37 teachers, who received specialised training and curriculum materials, or pupils, who
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39 would typically receive little or no alcohol education in their usual school year. Lack
40
41 of blinding in some data collectors may have also led to either under- or over-
42
43 reporting of alcohol use due to social desirability biases, although the use of
44
45 standardised data collection scripts partly mitigated against this.
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52 Our primary outcome assessment relied on self-report, which may have led to
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54 inaccurate reporting of alcohol use through memory, social desirability, and other
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3 biases.(39) Although adolescent self-reported alcohol questionnaires are generally
4 reliable,(40) there may be differences in reliability between early and late
5 adolescence,(19) and studies of recanting in substance use surveys suggest that this
6 may be an understudied bias in prevention research.(33) However, all students
7 received the same questionnaire and pictorial prompts, and the recall period for the
8 primary outcome used in this study was the previous 30 days, and so if bias had
9 existed, this would have been minimal, and equivalent across trial arms.
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20 Although the classroom component of STAMPP was based on the SHAHRP
21 programme, we did not detect a decrease in ARH. Previous studies of SHAHRP in
22 Australia and NI using quasi-experimental designs found that decreases in self-
23 reported ARH at 32 months were associated with intervention exposure.(21, 28)
24 Differences with the findings of this trial may be related to factors such as
25 methodology, pupil age, changes in the wider drinking culture and public health
26 environment, or other unmeasured cohort effects. Whilst there is a relationship
27 between HED in adolescence and health harms(1) we have planned further
28 exploratory analyses which will investigate ARH, patterns of reporting, and sub group
29 effects in more detail.
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44 Although we are mindful of differences in school autonomy, governance and
45 oversight, and acknowledge regional variability in alcohol use behaviours (e.g.(5)),
46 we believe that the findings of this trial are likely to be generalisable to other
47 geographies. Schools enrolled in the trial were drawn from urban and more rural
48 areas, and from across the socioeconomic gradient. Furthermore, sub group analyses
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3 showed that there were no differential intervention effects on the basis of school
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5 geography (i.e. NI vs Scotland).
6

7 **Conclusions**

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10 The results of this large cRCT provide support for the effectiveness of a combined
11
12 classroom and brief parental intervention for reducing HED, but not ARH, in young
13
14 adolescents. Effects on ARH may manifest later, but further research would be
15
16 required to clarify this.
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25
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33
34 Sandy Cunningham (Education Services, Glasgow). The views and opinions
35
36 expressed therein are those of the authors and do not necessarily reflect those of the
37
38 NIHR-PHR, NIHR, NHS or the Department of Health.
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44 **A. Author Contributions:** Sumnall had full access to all of the data in the study and
45
46 takes responsibility for the integrity of the data and the accuracy of the data
47
48 analysis. McKay wrote the first draft of the manuscript and subsequent versions;
49
50 Sumnall was project PI, contributed to the first draft and subsequent iterations of
51
52 the manuscript, and prepared and submitted the final version of the manuscript;
53
54 Percy conducted the statistical analysis and contributed to manuscript drafts; Agus,
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3 Foxcroft, Cole, Murphy, Doherty, Harvey all contributed to drafts and approved
4
5 the submission.
6

7 **B. Declaration of interests**

8
9
10 No personal competing interests declared. The sponsor University (LJMU) received
11
12 and administered a payment from the alcohol industry for printing of student
13
14 workbooks in the Glasgow trial site only. Percy reported that he has previously
15
16 received funding from the European Foundation of Alcohol Research (ERAB) in
17
18 relation to the development of statistical models for longitudinal data (2008-2010).
19
20 Foxcroft reported that his Department has previously received funding from the
21
22 alcohol industry for unrelated prevention programme training work. Sumnall reported
23
24 that his Department has previously received funding from the alcohol industry
25
26 (indirectly via the industry funded Drinkaware charity) for unrelated primary
27
28 research.
29
30

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43
44 funded. The research and intervention funders had no involvement in intervention
45
46 design; design and conduct of the study; collection, management, analysis, and
47
48 interpretation of the data; and preparation, review or approval of the manuscript.
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54 **D. Data**

1
2
3 Availability of data and materials: The datasets generated during and/or analysed
4 during the current study are not yet publicly available due to the authors undertaking
5 additional analyses and follow-on studies, but are available from the corresponding
6 author on reasonable request.
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10

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24 **List of supplementary information table captions**

25
26
27 **Table S1. Primary outcome alcohol consumption (HED) outcome analysis at 33**
28 **months**
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31 **Table S2 Secondary analysis: primary outcomes at T2**
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34 **Table S3 Secondary outcomes at T3**
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37 **Table S4 Secondary outcomes at T2**
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39
40 **Table S5 Correlations between baseline alcohol consumption (ever and last year**
41 **use) and baseline primary outcome indicators (HED and ARH)**
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44 **Table S6 Summary of intervention effects in primary outcome models (treatment**
45 **arm parameter estimates only) estimated on baseline drinker and non-drinker**
46 **sub-groups.**
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For peer review only

Online supplementary material

STAMPP - secondary outcomes and subgroup analyses

Secondary outcomes

A range of secondary outcomes were also examined within the study. These included the primary outcomes assessed at T2:

- *Binge drinking (T2)*: Self-reported alcohol use defined as self-reported consumption of >5 drinks, assessed at +24 months (T2) from baseline. This was dichotomised at none/one or more occasions. This outcome was assessed via a two level logistic regression model. Around 12.4% of respondents reported binge drinking at T2 using this measure. In the intervention arm binge drinking was reported by 10.9% (N=573) and in the control arm by 13.9% (N=722).
- *Drinking harms to self (T2)*: The number of self-reported harms (harms caused by own drinking) assessed at +24 months (T2) from baseline. Items included harms such as getting into a physical fight or being sick after drinking. The outcome was a count of the number of discrete harms reported (0-16) and was assessed by a two level negative binomial model. In the intervention arm 74.3% reported no drinking harms, while in the control arm 71.5% reported no harms.

In addition, a number of secondary outcomes at T3 and T2 were also examined, including:

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2
3 25 • *Lifetime drinking (T3)*: Whether the pupils had ever consumed a full drink of alcohol
4
5 26 at +33 months (T3) (two level logistic regression model).
6
7 27
8
9 28 • *Last year drinking (T3)*: Whether the pupils had consumed a full drink of alcohol in
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11 29 the last year, assessed at +33 months (T3) (two level logistic regression model).
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16 31 • *Last month Drinking (T3)*: Whether the pupils had consumed a full drink of alcohol in
17
18 32 the last month, assessed at +33 months (T3) (two level logistic regression model).
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22 34 • *Harm from others (T3 and T2)*: The number of self-reported harms experienced that
23
24 35 were the result of other people's drinking, assessed at both +33 months (T3) and +24
25
26 36 months (T2) from baseline (two level negative binomial models). Harms included
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28 37 being hit or having property damaged by someone who had been drinking.
29
30 38
31
32 39 • *Age of onset (T3 and T2)*: Self-reported age at which respondent first consumed a full
33
34 40 drink, assessed at both +33 months (T3) and +24 months (T2) from baseline (two
35
36 41 level Cox regression model).
37
38 42
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40 43 • *Unsupervised drinking (T3 and T2)*: Whether the pupils were permitted, by their
41
42 44 parents(s), to consume alcohol (with small group of friends or at parties) with no adult
43
44 45 present, assessed at both +33 months (T3) and +24 months (T2) from baseline (two
45
46 46 level logistic regression model).
47
48 47
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50 48 • *Number of drinks consumed (T3 and T2)*: Pupils were asked whether they usually
51
52 49 drank from a range of different alcohol drinks (beer, alcopops, spirits cider, wine,
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3 50 *Buckfast* [a popular brand of fortified wine, with caffeine], others) and if so, how
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5 51 much did they usually drink. The values for each drink were summed together to give
6
7 52 a total. As the underlying items continued decimals the total value was multiplied by
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9 53 10 to create whole numbers.
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14
15 56 The secondary outcome analysis also included covariates at level 1 (individual) and level 2
16
17 57 (school) where appropriate:
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20 59 **Level 1 covariates**

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24 60 *Relevant baseline drinking variable (T0)*: For each outcome, the corresponding baseline
25
26 61 characteristic was included in the model. Mean imputation was used to impute values for
27
28 62 those respondents who were missing on this variable. The only model not to include a
29
30 63 baseline covariate was age of onset.
31

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34 66 **Level 2 covariates**

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38 68 *Treatment Arm*: This was a binary covariate in which schools in the control arm were coded 0
39
40 69 and schools in the intervention arm were coded 1.
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48 71 *Free school meals* (Randomisation stratification factor): Schools were classified into three
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50 72 groups based on free school meal provision. The allocation was based on a tertile split based
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52 73 on information provided by head teachers on the proportion of pupils in receipt of free school
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74 meals: *Low* Free School Meal Provision (0-15.4%), *Moderate* Free School Meal Provision
75 (15.5-30.4%), *High* Free School Meal Provision (30.5% and above).

76

77 *School type* (Randomisation stratification factor): Given the larger number of schools in
78 Northern Ireland, an additional stratification factor was used in the randomisation. This was
79 school type (all boys' school/ all girls' school/coeducation school). Schools in
80 Glasgow/Inverclyde were all assigned to the co-education type. This indicator was used
81 represented by two dummy variables (co-education was the comparison category).

82

83 *Location*: A dummy variable was generated to indicate the location of the schools (Northern
84 Ireland/Scotland).

85 **Analysis of secondary outcomes**

86 Differences in self-reported alcohol use (defined as self-reported consumption of ≥ 6 units in a
87 single episode in the previous 30 days for males and ≥ 4.5 units for females - dichotomised at
88 never/one or more occasions) at + 12 months (t1) and +24 months (T2) were assessed using
89 two-level logistic regression models with covariates (baseline alcohol use, sex, SES and
90 location). Similar models were constructed for self-reported alcohol use in lifetime, last year
91 and previous month (all dichotomised) and for unsupervised alcohol use (drinking without
92 the supervision of parents/carers - dichotomised) at +12 months (T1), +24 months (T2) and
93 +33 months (T3).

94

95 A negative binomial model with covariates (baseline harms, sex, SES and location) was
96 estimated for the number of self-reported harms (harms caused by own drinking) at +12
97 months (T1) +24 months (T2). Similar models were estimated for the number of self-reported

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3 98 harms caused by the drinking of others and the number of drinks consumed in a ‘typical’ and
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5 99 the last use episodes at +12 months (T1), +24 months (T2) and +33 months (T3).
6
7 100

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9 101 Time to alcohol initiation (age at which a whole drink of alcohol was first consumed, not just
10
11 102 a sip or a shared drink) at +12 months (T1), +24 months (T2) and +33 months (T3) were
12
13 103 compared between trial arms by estimating a two-level Cox proportional hazards model in
14
15 104 those who had not already initiated alcohol consumption at baseline. The model controlled
16
17 105 for sex, SES and location.
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20 21 106 **Subgroup analyses**

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23 107 To explore differential treatment effects on the primary and secondary outcome measures,
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25 108 pre-specified interaction terms were fitted between trial arm and baseline measures thought to
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27 109 predict the effect of treatment. These were:

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30 110 • Age, in months, of pupil at baseline;
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32 111 • Gender;
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34 112 • Socioeconomic status (using the proportion of free school meals indicator);
35
36 113 • Alcohol use behaviour at baseline – age of initiation, use of alcohol in the
37
38 114 year prior to baseline, context of use (abstainer/supervised/unsupervised);
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41 115 • and in NI, a Grammar/Secondary school analysis.
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3 123 **Results**

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7 125 **Full primary outcome models**

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11 127 For reasons of space, the full primary outcome model is not presented in the main text. Table

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13 128 S1 presents the random intercept models for the primary outcomes at T3

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21 134 **Table S1. Primary outcome alcohol consumption (HED) outcome analysis at 33**
22 135 **months**

| | Estimate | S.E. | OR | P value |
|-----------------------------------|----------|-------|-------|---------|
| ITT Complete case analysis | | | | |
| <i>Within level</i> | | | | |
| Baseline Binge drinking | 1.395 | 0.093 | 4.036 | <0.001 |
| <i>Between Level</i> | | | | |
| Intervention Arm | -0.516 | 0.102 | | <0.001 |
| Free School Meals (tertile) | 0.239 | 0.073 | | 0.001 |
| School Type | | | | |
| Boys School Dummy | -0.186 | 0.200 | | 0.35 |
| Girls School Dummy | -0.546 | 0.266 | | 0.04 |
| Location (NI) | 0.422 | 0.109 | | <0.001 |
| School level residual variance | 0.176 | 0.035 | | <0.001 |
| Threshold (BngT3\$1) | 1.574 | 0.124 | | <0.001 |

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38 138 **Secondary analyses**

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42 140 Results of the secondary analyses are tabulated below. Table S2 presents the random

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44 141 intercept models for the primary outcomes at T2. Results were similar to those found at T3.

45
46 142 The baseline measures were significant, as was location. For the binge drinking outcomes

47
48 143 both free school meals (tertile split) and school type were significant. The intervention arm

49
50 144 was significant at a 0.05 level ($\beta=-0.241$; $p=0.041$). The 2.5% confidence intervals for this

51
52 145 parameter ranged from -0.010 to -0.473. However, it failed to reach the much stricter

53
54 146 threshold used in the primary analysis (0.025). It should be noted that the binge drinking

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3 147 indicator used at T3, and as specified in the DAP, was different that that used at T2. In
4
5 148 particular, this measure did not use gender specific splits, referred to drinks rather than units,
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7 149 and did not provide any visual guides to help with the estimation of amount consumed. This
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9 150 suggests that the significant intervention effect may have been partly dependent on the
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11 151 precision of the measurement instrument used to collect the primary outcome data. The age at
12
13 152 which differences in binge drinking were assessed may have been important when assessing
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15 153 intervention outcomes.
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18 154

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20 155 **Table S2 Secondary analysis: primary outcomes at T2**

| | Estimate | S.E. | OR | P value |
|---|----------|-------|-------|---------|
| Binge Drinking T2 (ITT CC population logistic model) | | | | |
| <i>Within level</i> | | | | |
| Baseline Binge drinking | 1.891 | 0.101 | 6.623 | <0.001 |
| <i>Between Level</i> | | | | |
| Treatment Arm | -0.241 | 0.118 | | 0.04 |
| Free School Meals (tertile) | 0.308 | 0.079 | | <0.001 |
| School Type | | | | |
| Boys School Dummy | -0.708 | 0.297 | | 0.02 |
| Girls School Dummy | -0.608 | 0.186 | | 0.001 |
| Location | 0.732 | 0.134 | | <0.001 |
| Residual variance | 0.214 | 0.047 | | <0.001 |
| Threshold (BngT2\$1) | 2.698 | 0.144 | | <0.001 |
| Harms to Self T2 (ITT CC population negative binomial model) | | | | |
| <i>Within level</i> | | | | |
| Baseline Harms drinking | 0.297 | 0.016 | | <0.001 |
| <i>Between Level</i> | | | | |
| Treatment Arm | -0.144 | 0.118 | | 0.22 |
| Free School Meals (tertile) | 0.162 | 0.086 | | 0.06 |
| School Type | | | | |
| Boys School Dummy | -0.247 | 0.302 | | 0.42 |
| Girls School Dummy | -0.246 | 0.200 | | 0.22 |
| Location | 0.716 | 0.132 | | <0.001 |
| Residual variance | 0.267 | 0.054 | | <0.001 |
| Intercepts (SHarmsT2) | -0.779 | 0.133 | | <0.001 |
| Dispersion | 4.478 | 0.304 | | <0.001 |

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49 157 Table S3 presents the outcome models for the secondary outcomes assessed at T3. None of
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51 158 the intervention parameter estimates were significant in these models.
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Table S3 Secondary outcomes at T3

| | Estimate | S.E. | OR | P value |
|---|----------|-------|-------|---------|
| Lifetime drinking T3 (ITT CC population logistic model) | | | | |
| <i>Within level</i> | | | | |
| Baseline Binge drinking | 2.070 | 0.081 | 7.922 | <0.001 |
| <i>Between Level</i> | | | | |
| Treatment Arm | -0.125 | 0.102 | | 0.22 |
| Free School Meals (tertile) | 0.040 | 0.070 | | 0.57 |
| School Type | | | | |
| Boys School Dummy | -0.182 | 0.209 | | 0.384 |
| Girls School Dummy | -0.501 | 0.233 | | 0.031 |
| Location | 0.597 | 0.113 | | <0.001 |
| Residual variance | 0.209 | 0.035 | | <0.001 |
| Threshold (LifeT3\$1) | 0.419 | 0.114 | | <0.001 |
| Last year drinking T3 (ITT CC population logistic model) | | | | |
| <i>Within level</i> | | | | |
| Baseline Last year drinking | 1.822 | 0.086 | 6.187 | <0.001 |
| <i>Between Level</i> | | | | |
| Treatment Arm | -0.126 | 0.096 | | 0.19 |
| Free School Meals (tertile) | 0.011 | 0.065 | | 0.87 |
| School Type | | | | |
| Boys School Dummy | -0.176 | 0.211 | | 0.40 |
| Girls School Dummy | -0.401 | 0.229 | | 0.08 |
| Location | 0.615 | 0.105 | | <0.001 |
| Residual variances | 0.177 | 0.032 | | <0.001 |
| Threshold (LYearT3\$1) | 0.485 | 0.103 | | <0.001 |
| Last month drinking T3 (ITT CC population logistic model) | | | | |
| <i>Within level</i> | | | | |
| Baseline Last month drinking | 1.329 | 0.114 | 3.779 | <0.001 |
| <i>Between Level</i> | | | | |
| Treatment Arm | -0.149 | 0.094 | | 0.11 |
| Free School Meals (tertile) | 0.114 | 0.069 | | 0.10 |
| School Type | | | | |
| Boys School Dummy | -0.333 | 0.213 | | 0.12 |
| Girls School Dummy | -0.330 | 0.237 | | 0.16 |
| Location | 0.381 | 0.104 | | <0.001 |
| Residual variances | 0.148 | 0.028 | | <0.001 |
| Threshold (LMonthT3\$1) | 1.459 | 0.102 | | <0.001 |
| Harms from others drinking T3 (ITT CC population NB model) | | | | |
| <i>Within level</i> | | | | |
| Baseline Harms (others) | 0.330 | 0.016 | | <0.001 |
| <i>Between Level</i> | | | | |
| Treatment Arm | 0.000 | 0.057 | | 0.10 |
| Free School Meals (tertile) | 0.077 | 0.042 | | 0.07 |
| School Type | | | | |
| Boys School Dummy | 0.117 | 0.116 | | 0.31 |
| Girls School Dummy | -0.070 | 0.172 | | 0.68 |
| Location | 0.167 | 0.063 | | 0.01 |
| Residual variance | 0.050 | 0.014 | | <0.001 |
| Dispersion | 1.301 | 0.071 | | <0.001 |
| Intercept | -0.733 | 0.061 | | <0.001 |
| Age of onset T3 (ITT CC population Cox regression model) | | | | |
| <i>Between Level</i> | | | | |
| Treatment Arm | -0.095 | 0.067 | | 0.16 |
| Free School Meals (tertile) | 0.054 | 0.047 | | 0.25 |

| | | | |
|---------------------------|--------|-------|---------|
| School Type | | | |
| <i>Boys School Dummy</i> | -0.299 | 0.146 | 0.04 |
| <i>Girls School Dummy</i> | -0.407 | 0.145 | 0.01 |
| Location | 0.344 | 0.075 | <0.001 |
| Residual variance | 0.097 | 0.017 | < 0.001 |

166

167

168 Table S4 presents the models for the secondary outcomes assessed at T2. Again, none of the

169 intervention parameter estimates were significant in these models.

170 **Table S4 Secondary outcomes at T2**

| | Estimate | S.E. | P value |
|--|----------|-------|---------|
| Harms from others drinking T2 (ITT CC population NB model) | | | |
| <i>Within level</i> | | | |
| Baseline Harms (others) | 0.421 | 0.017 | <0.001 |
| <i>Between Level</i> | | | |
| Treatment Arm | -0.058 | 0.060 | 0.33 |
| Free School Meals (tertile) | 0.132 | 0.044 | 0.003 |
| School Type | | | |
| <i>Boys School Dummy</i> | 0.144 | 0.108 | 0.18 |
| <i>Girls School Dummy</i> | 0.075 | 0.119 | 0.53 |
| Location | 0.255 | 0.071 | <0.001 |
| Residual variance | 0.058 | 0.011 | <0.001 |
| Dispersion | 1.032 | 0.078 | <0.001 |
| Intercept | -1.079 | 0.069 | <0.001 |
| Age of onset T2 (ITT CC population Cox regression model) | | | |
| <i>Between Level</i> | | | |
| Treatment Arm | -0.055 | 0.074 | 0.46 |
| Free School Meals (tertile) | 0.084 | 0.048 | 0.08 |
| School Type | | | |
| <i>Boys School Dummy</i> | -0.528 | 0.197 | 0.007 |
| <i>Girls School Dummy</i> | -0.453 | 0.169 | 0.007 |
| Location | 0.408 | 0.083 | <0.001 |
| Residual variance | 0.176 | 0.028 | <0.01 |
| Unsupervised drinking T2 (ITT CC population Logistic model) | | | |
| <i>Within level</i> | | | |
| Baseline unsupervised drinking | 2.114 | 0.097 | <0.001 |
| <i>Between Level</i> | | | |
| Treatment Arm | -0.087 | 0.100 | 0.39 |
| Free School Meals (tertile) | 0.166 | 0.066 | 0.01 |
| School Type | | | |
| <i>Boys School Dummy</i> | -0.306 | 0.217 | 0.16 |
| <i>Girls School Dummy</i> | -0.207 | 0.135 | 0.12 |
| Location | 0.669 | 0.112 | <0.001 |
| Residual variance | 0.170 | 0.038 | <0.001 |
| Threshold (Unsuper\$1) | 1.883 | 0.118 | <0.001 |
| Number of drinks T2 (ITT CC population NB model) | | | |
| <i>Within level</i> | | | |
| Baseline unsupervised | 0.170 | 0.013 | <0.001 |
| <i>Between Level</i> | | | |
| Treatment Arm | -0.088 | 0.096 | 0.36 |
| Free School Meals (tertile) | 0.125 | 0.068 | 0.07 |
| School Type | | | |
| <i>Boys School Dummy</i> | -0.574 | 0.259 | 0.03 |

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| | | | |
|---------------------------|--------|-------|--------|
| <i>Girls School Dummy</i> | -0.181 | 0.147 | 0.22 |
| Location | 0.583 | 0.105 | <0.001 |
| Residual variances | 0.153 | 0.035 | <0.001 |
| Intercept (NumDrkT2) | 2.836 | 0.106 | <0.001 |
| Dispersion (NumDrkT2) | 5.671 | 0.340 | <0.001 |

171 Subgroup analyses

172 To explore differential treatment effects on the primary measures interaction terms were
 173 fitted between trial arm and baseline measures thought to predict the effect of treatment.
 174 Initial pre-specified subgroup analysis examined baseline alcohol consumption (ever use, last
 175 year use, age of onset, unsupervised drinking). Given the high correlations between ever use,
 176 last year use and the two primary outcomes assessed at baseline (binge drinking and alcohol
 177 harms) (see Table), subgroup models were estimated on a base of just baseline drinkers (ever
 178 and last year use) to examine the possibility of the intervention having a differential impact
 179 on drinkers compared to non-drinkers at baseline.

180 **Table S5 Correlations between baseline alcohol consumption (ever and last**
 181 **year use) and baseline primary outcome indicators (HED and ARH)**

| | Ever use (T0) | Last year use (T0) |
|---------------|---------------|--------------------|
| HED (BngT0) | 0.426 | 0.434 |
| ARH (harmsT0) | 0.506 | 0.515 |

182
 183 For HED, the treatment arm was significant in both the drinker only models (both last year
 184 and ever use) and the corresponding non-drinker only models (
 185
 186 Table). This means that no differential intervention effect on binge drinking, dependent on
 187 baseline drinking, was detected. However, for ARH, whilst the intervention was associated
 188 with a significant reduction in the number of self-reported harms amongst drinkers (either
 189 defined as ever or last year use at baseline), it did not reduce self-reported harms amongst the
 190 non-drinkers at baseline. When the ever use and last year use subgroup effects were

191 examined via interaction terms (on the full CC population) the interaction terms for harms
 192 were non-significant, as were the interaction terms for age of onset and unsupervised
 193 drinking.

194

195 **Table S6 Summary of intervention effects in primary outcome models**
 196 **(treatment arm parameter estimates only) estimated on baseline drinker and**
 197 **non-drinker sub-groups.**

| | N | Estimate | S.E. | P value |
|---|------|----------|-------|---------|
| Binge drinking primary outcome models | | | | |
| 1. Treatment arm (<i>Limited to pupils reporting ever used alcohol at T0</i>) | 2011 | -0.504 | 0.127 | <0.001 |
| 2. Treatment arm (<i>Limited to pupils reporting never used alcohol at T0</i>) | 7145 | -0.570 | 0.123 | <0.001 |
| 3. Treatment arm (<i>Limited to pupils reporting used in last year at T0</i>) | 1617 | -0.484 | 0.141 | 0.001 |
| 4. Treatment arm (<i>Limited to pupils reporting didn't use in last year at T0</i>) | 7512 | -0.582 | 0.118 | <0.001 |
| Harms primary outcomes models | | | | |
| 1. Treatment arm (<i>Limited to pupils reporting ever used alcohol at T0</i>) | 2053 | -0.145 | 0.054 | 0.008 |
| 2. Treatment arm (<i>Limited to pupils reporting never used alcohol at T0</i>) | 7233 | -0.094 | 0.097 | 0.330 |
| 3. Treatment arm (<i>Limited to pupils reporting used in last year at T0</i>) | 1644 | -0.127 | 0.058 | 0.028 |
| 4. Treatment arm (<i>Limited to pupils reporting didn't use in last year at T0</i>) | 7615 | -0.069 | 0.096 | 0.314 |

Note: The primary outcome models summarised here were identical to the primary outcome model outlined above except for being restricted to just the subgroup members (drinkers and non-drinkers)

198

199 In the additional pre-specified subgroup analysis model estimated (age, gender), the
 200 corresponding interaction terms were all non-significant.

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Table S1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

| Section/Topic | Item No | Standard Checklist item | Extension for cluster designs | Page No * |
|----------------------------------|---------|--|---|-------------|
| Title and abstract | | | | |
| | 1a | Identification as a randomised trial in the title | Identification as a cluster randomised trial in the title | 1 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) ^{1,2} | See table 2 | 2 |
| Introduction | | | | 4 |
| Background and objectives | 2a | Scientific background and explanation of rationale | Rationale for using a cluster design | 6 |
| | 2b | Specific objectives or hypotheses | Whether objectives pertain to the cluster level, the individual participant level or both | 5, 11 |
| Methods | | | | 6 |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | Definition of cluster and description of how the design features apply to the clusters | 6 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | | N/A |
| Participants | 4a | Eligibility criteria for participants | Eligibility criteria for clusters | 6-7 |
| | 4b | Settings and locations where the data were collected | | 6 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Whether interventions pertain to the cluster level, the individual participant level or both | 8 & Table 1 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and | Whether outcome measures pertain to the cluster level, the individual participant level or both | 11 |

| | | | | |
|---|-----|---|---|-----|
| | | when they were assessed | | |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | | 12 |
| Sample size | 7a | How sample size was determined | Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or <i>k</i>), and an indication of its uncertainty | 12 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | | N/A |
| Randomisation: | | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | | 7 |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Details of stratification or matching if used | 7 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both | 7 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Replace by 10a, 10b and 10c | 7 |
| | 10a | | Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions | 6 |
| | 10b | | Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete | 7 |

| | | | | |
|---|-----|--|---|---------------|
| | | | enumeration, random sampling) | |
| | 10c | | From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation | 7 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | | 7-8 |
| | 11b | If relevant, description of the similarity of interventions | | 11 |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | How clustering was taken into account | 12 |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | | 14 |
| Results | | | | 15 |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome | 15 & Figure 1 |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | For each group, losses and exclusions for both clusters and individual cluster members | 15 & Figure 1 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | | 11 |
| | 14b | Why the trial ended or was stopped | | 16 |
| Baseline data | 15 | A table showing baseline demographic and clinical | Baseline characteristics for the individual and cluster levels as | 15 & Table 2 |

| | | | | |
|--------------------------------|-----|---|--|---|
| | | characteristics for each group | applicable for each group | |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | For each group, number of clusters included in each analysis | Table 2 |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome | 18 |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | | 18-19 |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | | 20 & online supplementary material |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms ³) | | 15 |
| Discussion | | | | 20 |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | | 21-22 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | Generalisability to clusters and/or individual participants (as relevant) | 23 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | | 23-24 |
| Other information | | | | |
| Registration | 23 | Registration number and | | 14 |

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| | | name of trial registry | |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | 6 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 24 and information included as part of journal submission process |

* Note: page numbers optional depending on journal requirements

For peer review only

Table 2: Extension of CONSORT for abstracts^{1,2} to reports of cluster randomised trials

| Item | Standard Checklist item | Extension for cluster trials |
|---------------------------|---|--|
| Title | Identification of study as randomised | Identification of study as cluster randomised |
| Trial design | Description of the trial design (e.g. parallel, cluster, non-inferiority) | |
| Methods | | |
| Participants | Eligibility criteria for participants and the settings where the data were collected | Eligibility criteria for clusters |
| Interventions | Interventions intended for each group | |
| Objective | Specific objective or hypothesis | Whether objective or hypothesis pertains to the cluster level, the individual participant level or both |
| Outcome | Clearly defined primary outcome for this report | Whether the primary outcome pertains to the cluster level, the individual participant level or both |
| Randomization | How participants were allocated to interventions | How clusters were allocated to interventions |
| Blinding (masking) | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | |
| Results | | |
| Numbers randomized | Number of participants randomized to each group | Number of clusters randomized to each group |
| Recruitment | Trial status ¹ | |
| Numbers analysed | Number of participants analysed in each group | Number of clusters analysed in each group |
| Outcome | For the primary outcome, a result for each group and the estimated effect size and its precision | Results at the cluster or individual participant level as applicable for each primary outcome |
| Harms | Important adverse events or side effects | |
| Conclusions | General interpretation of the results | |
| Trial registration | Registration number and name of trial register | |
| Funding | Source of funding | |

¹ Relevant to Conference Abstracts

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BMJ Open

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

| | |
|---------------------------------|--|
| Journal: | <i>BMJ Open</i> |
| Manuscript ID | bmjopen-2017-019722.R1 |
| Article Type: | Research |
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| Primary Subject Heading: | Public health |
| Secondary Subject Heading: | Addiction, Evidence based practice, Public health |
| Keywords: | alcohol, school based intervention, prevention, alcohol related harm, universal prevention, adolescents |
| | |

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Manuscripts



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3 **1 Steps towards alcohol misuse prevention programme (STAMPP): a school and**
4 **2 community based cluster randomised controlled trial**

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24 # Current address

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3 26 **Abstract** (Word count: 296)
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6 27 Objectives: To assess the effectiveness of a combined classroom curriculum and
7
8 28 parental intervention (The Steps Towards Alcohol Misuse Prevention Programme;
9
10 29 STAMPP), compared to alcohol education as normal (EAN), in reducing self-reported
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12 30 heavy episodic drinking (HED) and alcohol-related harms (ARH) in adolescents.
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17 32 Setting: 105 High schools in Northern Ireland (NI) and in Scotland.
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21 34 Participants: Schools were stratified by free school meal provision. Schools in NI
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23 35 were also stratified by school type (male/female/co-educational). Eligible students
24
25 36 were in school year 8/S1 (aged 11-12) at baseline (June 2012).
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30 38 Intervention: A classroom-based alcohol education intervention, coupled with a brief
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32 39 alcohol intervention for parents/carers.
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36 41 Primary Outcomes: (i) the prevalence of self-reported HED in the previous 30 days,
37
38 42 and (ii) the number of self-reported ARHs in the previous six months. Outcomes were
39
40 43 assessed using two level random intercepts models (logistic regression for HED and
41
42 44 negative binomial for number of ARHs).
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46 46 Results: At 33 months data were available for 5,160 intervention and 5,073 control
47
48 47 students (HED outcome), and 5,234 and 5,146 students (ARH outcome) respectively.
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52 49 Of those who completed a questionnaire at either baseline or 12 months (N=12,738),
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54 50 10,405 also completed the questionnaire at 33 months (81.7%). Fewer students in the
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57 52 Intervention group reported HED compared to EAN (17% versus 26%; odds
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3 51 ratio=0.60, 95% CI 0.49-0.73), with no significant difference in the number of self-
4
5 52 reported ARHs (incident rate ratio = 0.92, CI 0.78-1.05). Although the classroom
6
7 53 component was largely delivered as intended, there was low uptake of the parental
8
9 54 component. There were no reported adverse effects.
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14 56 Conclusions: Results suggest that STAMPP could be an effective programme to
15
16 57 reduce HED prevalence. Whilst there was no significant reduction in ARH, it is
17
18 58 plausible that effects on harms would manifest later.
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22 60 Trial Registration: The date of trial registration (ISRCTN47028486
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24 61 (<http://www.isrctn.com/ISRCTN47028486>) was 23/09/2011, and school recruitment
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26 62 began 01/11/2011.
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32 33 65 **Article Summary**

34 35 66 **Strengths and Limitations.**

- 36
37 67 • All data are longitudinal;
- 38
39 68 • The sample size was very large and attrition relatively low;
- 40
41 69 • Schools were independently randomised;
- 42
43 70 • Some of those involved in fieldwork were not blind to participant condition;
- 44
45 71 • Overall levels of alcohol-related harm were low.
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52 73 Keywords: alcohol; prevention; school based intervention; alcohol related harm;

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54 74 universal prevention; adolescents

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76

77 **Introduction**

78 Adolescence is a period when young people experiment with alcohol, and as they age
79 the amount and frequency of consumption increases.(1) Research has shown that
80 family socialisation factors such as approval of adolescent drinking and the provision
81 of alcohol in the home predicts drinking among adolescents and young adults (2-4)
82 An earlier onset of self-reported drunkenness and the establishment of regular alcohol
83 drinking is associated with a greater risk of alcohol-related problems in adulthood.(5)
84 There are also clear geographic and socioeconomic differences in the burden alcohol
85 places on the population, and these are closely associated with other major indicators
86 of ill health and health inequalities.(6-8)

87
88 Previous literature reviews have highlighted a lack of high quality trials of
89 universal school-based alcohol prevention programmes, and few approaches studied
90 have shown positive intervention effects.(9-15) However, while reviews have been
91 unable to recommend any single prevention initiative, many have concluded that
92 interventions that develop social skills appear to be superior to those that seek to
93 enhance only knowledge.(10-13) Guidance issued by the National Institute for Health
94 and Care Excellence (NICE) in the UK in 2007 called for partnerships between
95 schools and other stakeholders in efforts to prevent misuse.(16) Reviews of universal
96 alcohol prevention in family settings suggest that activities supporting parenting
97 skills, including establishing clear boundaries or rules and parental monitoring, may
98 be effective.(9, 17-19) Primary studies also suggest that when combined with a
99 school-based alcohol curriculum, provision of advice to parents about setting strict
100 rules around alcohol consumption reduces adolescent drinking.(20, 21) Indeed a

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3 101 recently-published systematic review reported that of ten identified combined child-
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5 102 and parent-based interventions, nine had reported significant and lasting positive
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7 103 effects on adolescent substance use (22).

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9 104 The Steps Towards Alcohol Misuse Prevention Programme (STAMPP)
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11 105 intervention combined a culturally adapted intervention based on the School Health
12
13 106 and Alcohol Harm Reduction Project (SHAHRP)(23) curriculum with a researcher-
14
15 107 developed brief parental intervention based on the Swedish Örebro Prevention
16
17 108 Program.(24) SHAHRP is an example of a resistance skills training programme, and
18
19 109 includes elements of alcohol-specific personal and social skills training.(25-28) In
20
21 110 accordance with the theoretical assumptions underlying such programmes, it includes
22
23 111 three main strategies: (i) teaching students to recognise high-risk situations, (ii)
24
25 112 increasing the awareness of external influences on behaviour, and (iii) combining self-
26
27 113 control (i.e. the ability to control responses, to interrupt undesired behavioural
28
29 114 tendencies and refrain from acting upon them) with refusal skills training (i.e. in order
30
31 115 to improve self-efficacy in avoiding unhealthy behaviours, but not with the
32
33 116 consequence of social disadvantage for the young person with their peers). The
34
35 117 knowledge delivered through SHAHRP (e.g. lessons on effects of alcohol, description
36
37 118 of alcohol units) was not assumed to have direct preventative effects, but instead
38
39 119 hypothesised to shape alcohol attitudes and support situation-specific decision
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41 120 making. The parental component was based on research indicating that restrictive
42
43 121 parenting practices (e.g., monitoring of children's alcohol use, healthy attitudes
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45 122 towards alcohol, alcohol rule-setting) was associated with reduced prevalence of
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47 123 children's alcohol use (21). When this approach was delivered alongside a classroom
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49 124 intervention in the Dutch Prevention of Alcohol Use in Students, programme effect
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3 125 was mediated through children's perceptions of parental rules, child self-efficacy, and
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5 126 child self-control.(29)

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9 128 It was hypothesised that fewer students in schools delivering STAMPP would
10
11 129 self-report: (i) past 30-day heavy episodic drinking (HED) at final follow-up (33
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13 130 months from baseline); and (ii) fewer self-reported alcohol-related harms (ARH) at
14
15 131 final follow-up than those in schools delivering alcohol education as normal (EAN).
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17 132 These primary aim of the research trial were to assess whether STAMPP was
18
19 133 effective in reducing self-reporting of these two indicators of alcohol misuse.
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25 135 **Materials and Methods**

26 27 28 136 **Study design**

29
30 137 This was a cluster randomised controlled trial (cRCT) of school children in Northern
31
32 138 Ireland (NI) and Glasgow/Inverclyde Education Authority (Scotland) areas in the
33
34 139 United Kingdom (UK) with schools as the unit of randomisation. The research was
35
36 140 approved by Liverpool John Moores University Research Ethics Committee
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38 141 (11/HEA/097). The trial protocol is available from
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40 142 <http://www.nets.nihr.ac.uk/projects/phr/10300209>.

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44 45 46 144 **Participants**

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48 145 The sampling frame comprised all mainstream post primary schools in NI (excluding
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50 146 those within the Eastern Health Board due to existing delivery of SHAHRP in that
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52 147 area) and in Glasgow/Inverclyde Local Authorities. All schools in the sampling frame
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3 148 were assessed for satisfaction of the inclusion criteria and willingness to participate in
4
5 149 the trial.

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7 150 A total of 105 schools were invited to participate in the trial, and all accepted;
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9 151 70 in NI, 30 in Glasgow Local Authority and five in Inverclyde Local Authority.
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11 152 Inclusion criteria were schools in NI and Scotland that taught students in school year
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13 153 8/S1 in the academic year 2011/2012 (aged 11/12 at randomisation). Exclusion
14
15 154 criteria were schools that did not include students in the specified school year, or only
16
17 155 provided non-mainstream or vocational education (e.g. pupil referral units, further
18
19 156 education colleges). Individual students with special educational needs in mainstream
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21 157 classrooms were excluded at the discretion of teachers as the intervention materials
22
23 158 had not been developed for use with this population.
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28 160 Participants were eligible students in the randomised schools, who consented
29
30 161 to participate. Opt in consent was obtained from school head-teachers/principals
31
32 162 before randomisation. Opt out consent from participants and their parents/guardians
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34 163 was obtained after randomisation. No schools withdrew from the trial and no pupils or
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36 164 parents/carers withdrew consent. Data was collected under examination-like
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38 165 conditions on school premises.
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41 42 43 44 167 **Randomisation and blinding**

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46 168 Schools were randomly assigned (1:1) to receive STAMPP or alcohol EAN before
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48 169 baseline data were collected. Randomisation was performed by an independent
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50 170 statistician blinded to the identity of the schools. All schools were stratified on Free
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52 171 School Meal Provision (FSM; low/moderate/high), which was taken as a proxy for
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3 172 socio-economic status. Schools in NI were also stratified by school-type
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5 173 (male/female/co-educational).

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9 175 Schools, students, intervention trainers and delivery staff (teachers) were not
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11 176 blinded to study condition. Data collection was undertaken by a team of researchers
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13 177 that included the trial manager and research assistants, some of whom were not
14
15 178 blinded to study condition.

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20 180 Data analysis of primary and secondary outcomes was undertaken by the trial
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22 181 statistician who was blinded to the study condition.

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25 26 27 183 **Procedures**

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29 184 STAMPP combined a school-based skills development curriculum, and a brief
30
31 185 parental intervention designed to support parents in setting family rules around
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33 186 drinking (see Table 1 for overview of the intervention). The classroom component of
34
35 187 STAMPP was based on the SHAHRP intervention and culturally adapted for the
36
37 188 settings of delivery.(30) It combined skills training, education, and activities designed
38
39 189 to encourage positive behavioural change.(23) See supplementary materials for more
40
41 190 details on the content of each lesson. It was a curriculum-based programme delivered
42
43 191 in two phases over a two year period. As part of the trial, the first phase was delivered
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45 192 when students were in school year 9/S2 (age 12-13 years) and the second phase was
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47 193 delivered during the subsequent year.

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53 195 The parental component of STAMPP was developed by the trial team and was
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55 196 based on the programme structure of Koutakis and colleagues (24), and Koning and

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3 197 colleagues. (20, 21) The component differed in two main ways to these earlier
4
5 198 programmes. Firstly, as part of STAMPP, delivery of a single parental component
6
7 199 coincided with the delivery of phase two of the classroom curriculum, whereas in
8
9 200 Koutakis and Koning, parents' evenings were held several times over the intervention
10
11 201 delivery phase. Secondly, the session was partly based upon guidelines included in the
12
13 202 UK Chief Medical Officers' 2009 guidelines for drinking in childhood (31). All
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15 203 intervention pupil parents, regardless of whether they had attended the evening or not,
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17 204 were mailed an information leaflet a few weeks after the parental session which
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20 205 reinforced the discussion points.
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206 **Table 1.** Stages in the STAMPP Trial

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| Stage | Description |
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| Recruitment of schools | <ul style="list-style-type: none"> • Schools in Glasgow Local Authority (n = 30) were recruited as a complete group following negotiations with Education Services • Schools in Inverclyde (n = 5) were recruited following a meeting with the Headteachers/Principals to discuss the practicalities of the trial. • Schools in Northern Ireland (n = 70) were recruited individually in the following process: letter of information; follow-up telephone call; individual meeting with Headteacher/ Principals; agree yes/no. |
| Training of teachers | <ul style="list-style-type: none"> • One-day training events were held in each study site before both phases of delivery of the classroom component. Training for the following academic year (from September onwards) took place in the preceding June. • Training involved lectures on alcohol (e.g. effects of alcohol use; prevalence rates; risk and protective factors for alcohol use), sharing experiences on previous delivery of the programme, and skills rehearsal for each of the SHAHRP lessons. • Training involved examination of each of the SHAHRP Lessons which covered: Myths about Alcohol; Units of Alcohol; Reasons why people do/don't drink; Alcohol and the Body; Consequences of 'levels' of drinking; Blood Alcohol Concentration; Social and Personal Harms; Alcohol Policy; Alcohol and the Media; Advice for Teenagers; A 'Night Out'; Pressures faced by Young Drinkers; Scenario-based discussion. • Each lesson was scheduled to last one lesson period (approximately 40 minutes) and delivered once a week |

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| | <ul style="list-style-type: none"> Teachers were provided with support materials (CD-ROMS, workbooks) at each training session to help implement the lessons. |
| Intervention Period | <ul style="list-style-type: none"> The intervention period was September to November in both academic years. Phase One involved six lessons and Phase Two, four lessons. Schools were asked to complete all lessons within the three-month delivery window in both phases. The Parental Brief Intervention coincided with delivery of Phase Two when the children were in their third year of secondary school and took place in the evening on Intervention school premises The intervention included a brief presentation on the UK Chief Medical Officers’ guidelines on alcohol use by young people, and a discussion on setting family rules on alcohol. All Intervention student parents, regardless of whether they had attended the evening or not, were mailed a leaflet which reinforced these points a few weeks after the parental session Final data collection for the primary outcome took place one year after all elements of the intervention had been delivered. |

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3 The control group participants continued with alcohol EAN within their
4 school. In NI, alcohol-related education is delivered in the context of the Personal
5 Development dimension of Learning for Life and Work (32) while in Scotland,
6 alcohol education is delivered within the context of Curriculum for Excellence (33).
7 In both contexts guidelines are offered to schools, however, the precise nature and
8 duration of EAN is at the discretion of individual school Managers. Parents/carers of
9 control students did not receive the STAMPP intervention or materials, but may have
10 been exposed to alcohol intervention activities in the community as part of
11 independent provision.
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24 Questionnaires were administered to participants at baseline in June 2012 and
25 at three follow-ups: +12, +24, and +33 months. All students that were present at
26 baseline or joined participating schools prior to delivery of Phase 1 of the intervention
27 were included in the analyses. Parents/carers were asked to complete a short postal
28 questionnaire, which coincided with delivery of the information leaflet. Alcohol rules
29 were assessed using a 10-item scale to measuring the degree to which parents/carers
30 permitted their children to consume alcohol in various situations, such as 'in the
31 absence of parents at home' or 'at a friend's party' ($\alpha = 0.86 - 0.90$). (34) Parental
32 alcohol self-efficacy was assessed using a three item scale assessing the level of
33 confidence the parent/carer had in their own ability to prevent their child from
34 drinking ($\alpha = 0.67$). (35) This data was collected to inform future mediation analysis
35 and is not reported here.
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52 Outcomes

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3 The study had two primary outcomes at 33 months; (i) the prevalence of self-reported
4 HED drinking in the previous 30 days (HED defined as the consumption of ≥ 6 units
5 [males]/ ≥ 4.5 units [females] on one or more occasions) and (ii) the number of self-
6 reported harms (caused by own drinking) in the previous six months in students. Pre-
7 specified secondary outcomes are described in the online supplementary material,
8 except for those related to the cost-effectiveness analysis which will be reported
9 elsewhere. The original primary outcome was self-reported frequency of consumption
10 of >5 'drinks' in a single drinking episode. However, concerns arose because it
11 became clear that >5 'drinks' could refer to drinks of different alcohol strength and
12 volume. As the objective of the intervention was to reduce HED, the primary outcome
13 was changed to consumption of ≥ 6 units for males, and ≥ 4.5 units for females – both
14 are 1.5 times the Chief Medical Officer's maximum daily guideline for adults,(31)
15 and this was ratified by the independent Study Steering Committee. This change was
16 implemented before the final wave of data collection, before unblinding, and before
17 any analysis of trial outcome measures at any data collection point had been
18 undertaken.

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39 To assess the HED primary outcome, participants were presented with pictorial
40 prompts of how much alcohol $\geq 6/\geq 4.5$ UK units represents. Pictures presented the
41 most popular drinks consumed in the two study areas and respondents were asked to
42 report the frequency of consuming this amount of alcohol over the previous month.
43 Harms associated with own use of alcohol were measured using a 16-item scale
44 developed for the Australian SHAHRP trial (internal consistency 0.9).(36)
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Participants were asked to indicate on a Likert scale how many times in the past six
months they had experienced the individual harm. For example, participants were

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3 asked to report frequency of having a hangover after drinking, or if they had got into a
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5 physical fight when drinking.
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8 9 **Statistical analysis**

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11 It was calculated that a sample size of 90 schools (45 per study arm; 80 students per
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13 school) would be powerful enough (80%; $\alpha = 0.05$; ICC = 0.09 based on data from the
14
15 Belfast Youth Development Study (37)) to detect a standardised effect size of $\delta = 0.2$,
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17 or a 10% absolute reduction in risk (51% vs. 41%) for the primary outcome of HED.
18
19 Assuming 20% attrition within each cluster (from 100 to 80 students), the target
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21 sample size was 90 schools and 9000 students at baseline.
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28 Summary statistics on school and student recruitment, withdrawal and dropout
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30 were collated for both trial arms and reported as a participant flow diagram for
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32 reporting of cRCT (Fig 1). Outcome measure scores from the questionnaires were
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34 summarised and tabulated for the trial arms.
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39 The outcome analysis was an Intention to Treat (ITT) analysis using the
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41 Complete Case (CC) population such that all cases were assessed regardless of
42
43 intervention and intervention dosage. Logistic regression models estimated the
44
45 association between STAMPP and the odds of self-reported HED. Negative binomial
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47 regression models estimated the association between STAMPP and the number of
48
49 ARH. All models included school-level random intercepts to account for correlation
50
51 due to clustering of students within schools. All models adjusted for factors used to
52
53 stratify randomization and the outcome's corresponding value at baseline. For details
54
55 of analysis of secondary outcomes please see the supplementary material. For each
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3 primary and secondary outcome, a statistically significant result was concluded if the
4
5 p -value for the treatment arm explanatory variable was <0.025 .
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9 Sensitivity analyses included repetition of the primary outcome analysis using
10 the ITT population with different missing data models. These included a “best case”
11 (missing set to non-HED), “worst” case (missing set to HED), “conservative case”
12 (missing in control arm set to non-HED, missing in intervention arm set to HED) and
13 multiple imputation with 50 imputed data sets.
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22 To explore differential intervention effects on the primary measures, pre-
23 specified interaction terms were fitted between trial arm and baseline measures
24 thought to predict the effect of intervention on primary outcomes. These were: age
25 (months) at baseline; gender; socioeconomic status (proportion of students in receipt
26 of FSM tertile split); alcohol use behaviour at baseline – age of initiation, use of
27 alcohol in the year prior to baseline, context of use (abstainer/supervised/
28 unsupervised); and in NI, Grammar/Secondary school.
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39 Process outcomes were assessed across eight pre-specified domains (including
40 intervention acceptability and assessment of the content of EAN), using nine data
41 sources. Methodologies included focus groups with students, an online survey with
42 teachers, and interviews with senior school staff and stakeholders. Fidelity and
43 completeness of delivery were assessed using bespoke tools and calculation of
44 participation rates at the parent/carer evening.
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3 Data cleaning, data management and preliminary analysis were undertaken
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5 using IBM SPSS version 20+. Mplus 7.11 was used for all analyses and Stata/IC 12.0
6
7 was used to verify Mplus models and generate odds ratios (OR).
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11 The trial was registered, number ISRCTN47028486.
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13

14 15 16 **Ethics approval and consent to participate**

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18 The research was approved by Liverpool John Moores University Research Ethics
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20 Committee (11/HEA/097). Participants were eligible students in the randomised
21
22 schools, who consented to participate. Consent was obtained from school head-
23
24 teachers/principals before randomisation. Consent was obtained from participants and
25
26 their parents/guardians after randomisation. This was through an opt-out method as
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28 opt-in written consent was not required by the ethics committee.
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32 33 34 **Results**

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37 Fig 1 shows participant flow through the trial. School recruitment began in November
38
39 2011 and ended in January 2012. As this was a cRCT of an intervention taking place
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41 across several years, student numbers refer to those who completed the questionnaire
42
43 at each data collection period. No participant or parent/carer requested data were
44
45 retrospectively removed from analysis. Multiple data collection 'mop up' visits were
46
47 undertaken with schools, and attrition represents students who were absent on data
48
49 collection days rather than formal drop out. Of the full sample (those who completed
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51 a questionnaire at either baseline or 12 months, N=12,738), 10,405 also completed the
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53 questionnaire at 33 months (81.7%). There was a higher attrition rate amongst
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1
2
3 students who were male (19.0%), in receipt of FSM (25.8%), and had used alcohol at
4
5 baseline (25.4%). There was little difference in attrition between the control and
6
7 intervention arms of the trial (around one percentage point difference). Attrition also
8
9 varied by location, with a higher rate in Scotland (24.0%) compared to NI (15.0%).
10
11 Across schools attrition varied from 1.5% to 32.0%. There were no unintended harms
12
13 or adverse effects reported.
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18 **INSERT FIGURE 1 HERE**
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23 Baseline data collection took place in June 2012 with the following follow up
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25 data collection points: 12 months (after delivery of phase one of the classroom
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27 component); 24 months (after delivery of the parental intervention and phase two of
28
29 the classroom component); and 33 months. The trial ended as planned after final data
30
31 collection and analysis.
32
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36 Baseline characteristics of students (n=11,316) are presented in Table 2. No
37
38 significant differences in baseline characteristics were detected between control and
39
40 intervention arms. Overall parental/carer participation was low. A total of 319
41
42 parent(s)/carer(s) attended the intervention evenings in NI (9% of those eligible) and
43
44 63 parents attended in Scotland (2.5%). With respect to the follow-up mailed
45
46 intervention, 1074 returns were received from parent(s)/carer(s) in NI (a 31% return)
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48 and 440 in Scotland (18%).
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53 **INSERT TABLE 2 HERE**
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Table 2. Baseline characteristics of students according to study condition.

| | Control | Intervention |
|--------------------------|-------------------------|-------------------------|
| | n (% _{valid}) | n (% _{valid}) |
| Total (n=11,316) | 5567 (49.2) | 5749 (50.8) |
| <i>Gender</i> | | |
| Male | 2787 (51.1) | 2834 (50.0) |
| Female | 2670 (48.9) | 2829 (50.0) |
| Missing | 110 | 86 |
| <i>Free School Meals</i> | | |
| No | 4289 (77.3) | 4436 (77.5) |
| Yes | 1258 (22.7) | 1290 (22.5) |
| Missing | 20 | 23 |
| <i>Location</i> | | |
| NI | 3469 (62.3) | 3554 (61.8) |
| Scotland | 2098 (37.7) | 2198 (38.2) |
| Missing | 0 | 0 |
| <i>HED^a</i> | | |
| No | 5082 (92.2) | 5261 (92.4) |
| Yes | 432 (7.8) | 431 (7.6) |
| Missing | 53 | 57 |
| <i>Ethnicity</i> | | |
| White | 4492 (95.3) | 4495 (94.5) |
| Non-white | 248 (4.5) | 293 (5.5) |
| Missing | 827 | 961 |

Note: The percentages are calculated on the basis of the complete cases only.

^a Assessed at baseline as consuming > 5 drinks in one or more episodes in the last 30 days.

Table 3 shows the count and percentages of respondents reporting drinking above the primary outcome threshold ($\geq 6/\geq 4.5$ units) at 33 months, and the adjusted model results by study arm (OR; Incidence rate ratio, IRR). Around one in 5 participants reported at least one episode in the last 30 days. The prevalence of episodes was around nine percentage points higher in the control group (26%) than in the intervention group (17%). Taking the within (pupil) level variance (fixed at 3.29) and the between (school) level variance (0.454 for the full sample), estimated using a null two level model, the corresponding ICC for the full sample was 0.121. Supplementary Tables S1 and S2 show the full random intercept models for the primary outcomes at 33 months.

Table 3 Primary outcomes at 33 months by study group

| | Unadjusted results | | Adjusted model results | |
|------------------------|-------------------------|-------------------------|------------------------|-----------|
| | Control | Intervention | OR/IRR | 95% CI |
| | N (% _{valid}) | N (% _{valid}) | | |
| HED (frequency) | | | | |
| None | 3773 (74.4) | 4281 (83.0) | 0.60 | 0.49-0.73 |
| One or more occasion | 1300 (25.6) | 879 (17.0) | | |
| <i>Missing</i> | <i>1286</i> | <i>1219</i> | | |
| ARH (frequency) | | | | |
| None | 3126 (60.7) | 3408 (65.1) | 0.92 | 0.78-1.05 |
| One or more occasion | 2020 (39.3) | 1826 (34.9) | | |
| <i>Missing</i> | <i>1213</i> | <i>1145</i> | | |
| Median (IQR) | 0 (2) | 0 (3) | | |

OR, odds ratio; IRR, incidence rate ratio; HED, Heavy episodic drinking; ARH, Alcohol related harms.

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5 Fig 2 displays the count of respondents reporting ARH at 33 months by study
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7 group. Around two thirds of students (63%) reported no alcohol-related harms. The
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9 median number of harms was equivalent in each study arm (0), while the interquartile
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11 range was smaller in the intervention arm than in the control arm (IQR = 2 and 3
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13 respectively).

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18 **INSERT FIGURE 2 HERE**
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22 At the school level, the parameter estimates were significant for the
23
24 intervention arm (estimate = -0.516, SE=0.102; $p < 0.001$). Schools in the intervention
25
26 arm had lower levels of HED (their intercepts) than those in the control arm (OR =
27
28 0.596, 95% CI 0.490 – 0.725). This represents a significant intervention effect.
29
30 However, with respect to ARH, the intervention indicator was non-significant
31
32 suggesting no difference between the intervention and control schools (estimate -
33
34 0.101, SE = 0.083; $p = 0.222$; IRR = 0.916, 95% CI 0.780 – 1.052). Across three of
35
36 the sensitivity analysis models (best case; worst case; and multiple imputed data
37
38 models) the intervention arm coefficient remained significant and retained the same
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40 sign for HED (i.e. being a school in the intervention arm was associated with having a
41
42 lower intercept), while ARH remained non-significant. The only exception was the
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44 conservative case model, where both primary outcomes were non-significant.
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50 When the primary measures were assessed at +24 months, as secondary
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52 outcomes, the intervention arm was significant at a 0.05 level ($\beta=-0.241$; $p=0.041$) in
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54 the HED model, but failed to reach the much stricter threshold used within this study
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3 (p<0.025) (Supplementary Table S3). The intervention arm was also non-significant
4
5 when the ARH outcome was assessed at +24 months ($\beta=-0.144$; $p=0.22$)
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7 (Supplementary Table S3). In all the other secondary outcomes, including those
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9 assessed at +33 months (Supplementary Table S4) and at +24 months (Supplementary
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11 Table S5), the intervention arm was non-significant.
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16 **Discussion**

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21 In a large cRCT we found that the STAMPP intervention reduced self-
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23 reported heavy episodic drinking (HED) in the past 30 days at 33 months follow-up
24
25 from baseline, compared with education as normal (EAN), but not alcohol-related
26
27 harms (ARH) associated with own drinking. There were no clear or consistent effects
28
29 identified in planned secondary or sub-group analyses (age, gender, SES, alcohol use
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31 at baseline, location [Scotland vs NI]). It is possible that longer-term follow-up and/or
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33 emphasis on those drinking might reveal such effects, especially with regard to self-
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35 reported ARH, which were low in both control and intervention students. The
36
37 intervention was well received by both pupils and teachers.
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43 Key strengths of the trial were the large sample size (schools and students), low rates
44
45 of attrition (no schools dropped out), and relatively high rates of matched data (>80%)
46
47 across survey waves. This means that the analyses were sufficiently powered. There
48
49 also appeared to be no comparator bias, as monitoring of delivery of EAN in
50
51 intervention schools showed that this did not include alcohol education. A major
52
53 limitation of the work was the failure to attract parents/carers to the brief intervention
54
55 evening, despite the support of many of the schools. Although all intervention
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3 students received a mailed follow up leaflet that reinforced the main messages of the
4
5 parental intervention, relatively low rates of return of the parental questionnaire
6
7 suggest that only a minority may have read the mailed information. In contrast,
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9 parental participation in the structurally similar (i.e. classroom and parental
10
11 components) Swedish Örebro Prevention Program, and the Dutch Prevention of
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13 Alcohol use in Students (PAS) alcohol prevention programmes were relatively high.
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15 (24, 38) Because we chose a parental intervention based on one with face-to-face
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17 contact (21), we attempted to engage parents at school-based meetings. However, it is
18
19 possible that the use of a DVD or the creation of a Web-based presentation could have
20
21 served this purpose equally well.(22) Universal interventions such as STAMPP
22
23 require a range of recruitment strategies as there will be different barriers to, and
24
25 facilitators of, attendance in parental/carer-based actions. Research is therefore
26
27 needed to assess the relative efficacy of recruitment strategies such as incentives,
28
29 mass media campaigns, the removal of barriers to attendance (e.g. providing transport
30
31 and childcare), and the use of key community recruiters (influential individuals and
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33 organisations).(39) Furthermore, it is also important to understand if some
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35 parent/carer subgroups (e.g. differentiated on child drinking risk) are more likely to
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37 respond to particular recruitment strategies, and if this will lead to recruitment biases.
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44 Although we conducted an ITT analysis which helped to preserve sample size, the
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46 achieved participation rates are likely to reflect parental/carer attendance in routine
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48 UK practice.(40-42) This meant that we were unable to draw any confident inferences
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50 about the combined impact of the school and parental intervention (*cf* (29)), or the
51
52 relative contribution of each component. In practical terms, this means that although
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54 the analysis presumed delivery of the combined intervention, discussions with
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3 stakeholders about research findings and future delivery are likely to focus on the
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5 classroom component (i.e. culturally adapted SHAHRP). However, it is noteworthy
6
7 that in the PAS programme (21), the classroom component alone did not produce
8
9 changes in alcohol use behaviours, and these were only observed in pupils receiving
10
11 the combined intervention. Subsequent mediation analysis of trial data suggested that
12
13 reduced rate of frequency of drinking or weekly drinking, was mediated by changes in
14
15 parental rules and attitudes towards alcohol (i.e. more strict rules and attitudes were
16
17 developed). It is therefore important that similar analyses are undertaken to better
18
19 understand mediators of behaviour change in STAMPP recipients. Other weaknesses
20
21 of the study included the lack of blinding in intervention delivery and in some data
22
23 collectors. It is plausible that lack of blinding in delivery may led to either under- or
24
25 over-reporting of alcohol use due to social desirability biases, but using an EAN
26
27 comparator meant that it was not possible to conceal intervention allocation from
28
29 teachers, who received specialised training and curriculum materials, or pupils, who
30
31 would typically receive little or no alcohol education in their usual school year. Lack
32
33 of blinding in some data collectors may have also led to either under- or over-
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35 reporting of alcohol use due to social desirability biases, although the use of
36
37 standardised data collection scripts mitigated against this.
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44 Our primary outcome assessment relied on self-report, which may have led to
45
46 inaccurate reporting of alcohol use through memory, social desirability, and other
47
48 biases.(43) Although adolescent self-reported alcohol questionnaires are generally
49
50 reliable,(44) there may be differences in reliability between early and late
51
52 adolescence,(20) and studies of recanting in substance use surveys suggest that this
53
54 may be an understudied bias in prevention research.(37) However, all students
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3 received the same questionnaire and pictorial prompts, and the recall period for the
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5 primary outcome used in this study was the previous 30 days, and so if bias had
6
7 existed, this would have been minimal, and equivalent across trial arms.
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11 Although the classroom component of STAMPP was based on the SHAHRP
12
13 programme, we did not detect a decrease in ARH. Previous studies of SHAHRP in
14
15 Australia and NI using quasi-experimental designs found that decreases in self-
16
17 reported ARH at 32 months were associated with intervention exposure.(23, 30)
18
19 Differences with the findings of this trial may be related to factors such as
20
21 methodology, pupil age, changes in the wider drinking culture and public health
22
23 environment, or other unmeasured cohort effects. Whilst there is a relationship
24
25 between HED in adolescence and health harms(1) we have planned further
26
27 exploratory analyses which will investigate ARH, patterns of reporting, and sub group
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29 effects in more detail.
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35 Although we are mindful of differences in school autonomy, governance and
36
37 oversight, and acknowledge regional variability in alcohol use behaviours (e.g.(5)),
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39 we believe that the findings of this trial are likely to be applicable to other
40
41 geographies. Schools enrolled in the trial were drawn from urban and more rural
42
43 areas, and from across the socioeconomic gradient. Furthermore, sub group analyses
44
45 showed that there were no differential intervention effects on the basis of school
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47 geography (i.e. NI vs Scotland).
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52 **Conclusions**

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3 The results of this large eRCT provide support for the effectiveness of a combined
4 classroom and brief parental intervention for reducing HED, but not ARH, in young
5 adolescents. Effects on ARH may manifest later, but further research would be
6
7 required to clarify this.
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10

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36 **A. Author Contributions:** Sumnall had full access to all of the data in the study and
37 takes responsibility for the integrity of the data and the accuracy of the data
38 analysis. McKay wrote the first draft of the manuscript and subsequent versions,
39 and submitted the final version; Sumnall was project PI, contributed to the first
40 draft and subsequent iterations of the manuscript, and prepared the final version of
41 the manuscript; Percy conducted the statistical analysis and contributed to
42 manuscript drafts; Agus, Foxcroft, Cole, Murphy, Doherty, Harvey all contributed
43 to drafts and approved the submission.
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53 **B. Declaration of interests:** No personal competing interests declared. The sponsor
54 University (LJMU) received and administered a payment from the alcohol
55
56

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2
3 industry for printing of student workbooks in the Glasgow trial site only. Percy
4 reported that he has previously received funding from the European Foundation of
5 Alcohol Research (ERAB) in relation to the development of statistical models for
6 longitudinal data (2008-2010). Foxcroft reported that his Department has
7 previously received funding from the alcohol industry for unrelated prevention
8 programme training work. Sumnall reported that his Department has previously
9 received funding from the alcohol industry (indirectly via the industry funded
10 Drinkaware charity) for unrelated primary research.

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26 had no involvement in intervention design; design and conduct of the study;
27 collection, management, analysis, and interpretation of the data; and preparation,
28 review or approval of the manuscript.

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39 **D. Data:** Availability of data and materials: The datasets generated during and/or
40 analysed during the current study are not yet publicly available due to the authors
41 undertaking additional analyses and follow-on studies, but are available from the
42 corresponding author on reasonable request.
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3 **Fig 1. School and participant flow diagram - STAMPP Trial. Analysis was**
4 **conducted at 33 months on students who had completed each of the primary**
5 **outcome measures. N = number of schools; n = student numbers**
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11 **Fig 2. Count of school children reporting one or more alcohol related harms by**
12 **study arm**
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16 17 18 19 20 **References**

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40 adolescence. Alcohol and alcoholism (Oxford, Oxfordshire). 2004;39(4):362-8.
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51 **List of supplementary information table captions**

52
53 **Table S1. Primary outcome (HED) outcome analysis at +33 months**

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55 **Table S2. Primary outcome (ARH) outcome analysis at + 33 months**

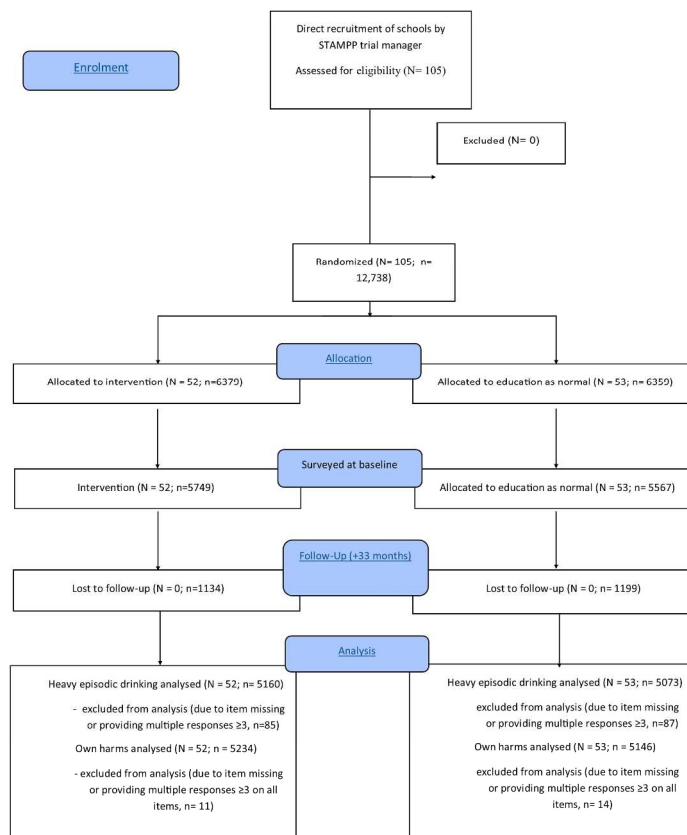
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Table S3. Secondary analysis: primary outcomes at +24 month

Table S4. Secondary outcomes at +33 months

Table S5. Secondary outcomes at +24 months

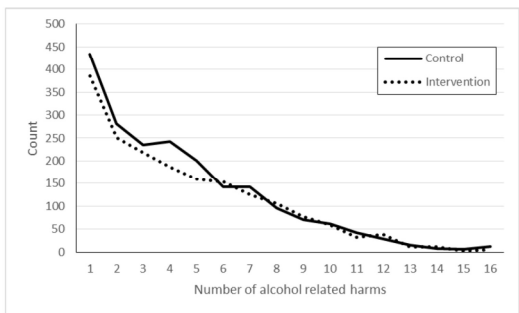
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School and participant flow diagram - STAMPP Trial. Analysis was conducted at 33 months on students who had completed each of the primary outcome measures. N = number of schools; n = student numbers

209x297mm (300 x 300 DPI)

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Count of school children reporting one or more alcohol related harms by study arm

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ONLINE SUPPLEMENTARY MATERIAL

INTERVENTION CONTENT

The Classroom component of the intervention was composed of six lessons in the second year of High school (Phase one), and four lessons in the third year (Phase two). The content of these is detailed below.

Phase 1

Lesson 1: Alcohol True or False (10 statements); Introduction to what is meant by 'Units' of alcohol; Introduction to the extent of harm that alcohol misuse can cause.

Lesson 2: Making Choices – why people choose to drink (and assessing the merit of those choices); Making Choices – why people may choose not to drink; Introduction to Alcohol and the Body.

Lesson 3: Units of Alcohol – more detail including unit content of drinks; Relating consumption to consequences; Short Quiz to recap information.

Lesson 4: Blood Alcohol Concentration; Alcohol harms in various societal contexts (with other drugs, in families, in communities, driving, and sexual behaviour).

Lesson 5: Exercise – 'What would you do to reduce harms?' Critical examination of alcohol and the Media.

Lesson 6: Real Life Scenarios, plus recap.

Phase 2

Lesson 1: Brief recap from previous year; Alcohol and the Body – long term versus short term; Quiz.

Lesson 2: A night out – examining dangers, laws, problems, pressures and consequences.

Lesson 3: Vulnerability – two scenarios examined from the point of view of 'victim', friends, and 'perpetrator'; Planning for a safe night out with friends.

Lesson 4: Ranking Risk; What would you advise a friend to do?

STAMPP – FULL PRIMARY OUTCOME MODELS, SECONDARY OUTCOMES AND SUBGROUP ANALYSES

FULL PRIMARY OUTCOME MODELS

For reasons of space, the full primary outcome models were not presented in the main text.

Table S1 presents the parameter estimates from a two level random intercepts logistic regression model for the heavy episodic drinking (HED) primary outcome at T3.

Table S1. Primary outcome (HED) outcome analysis at + 33 months

| | Estimate | S.E. | OR | P value |
|-----------------------------------|----------|-------|-------|---------|
| ITT Complete case analysis | | | | |
| <i>Within level</i> | | | | |
| Baseline HED | 1.395 | 0.093 | 4.036 | <0.001 |
| <i>Between Level</i> | | | | |
| Intervention Arm | -0.516 | 0.102 | | <0.001 |
| Free School Meals (tertile) | 0.239 | 0.073 | | 0.001 |
| School Type | | | | |
| Boys School Dummy | -0.186 | 0.200 | | 0.35 |
| Girls School Dummy | -0.546 | 0.266 | | 0.04 |
| Location (NI) | 0.422 | 0.109 | | <0.001 |
| School level residual variance | 0.176 | 0.035 | | <0.001 |
| Threshold (BngT3\$1) | 1.574 | 0.124 | | <0.001 |

Table S2 gives the parameter estimates from a two level random intercepts negative binomial model for the drinking harms primary outcome at T3.

Table S2. Primary outcome (ARH) outcome analysis at + 33 months

| | Estimate | S.E. | P value |
|-------------------------------|----------|-------|---------|
| Complete case analysis | | | |
| <i>Within level</i> | | | |
| Baseline Harms | 0.211 | 0.011 | <0.001 |
| <i>Between Level</i> | | | |
| Intervention Arm | -0.101 | 0.083 | 0.222 |
| Free School Meals (tertile) | 0.168 | 0.061 | 0.006 |
| School Type | | | |
| Boys School Dummy | -0.083 | 0.204 | 0.685 |
| Girls School Dummy | -0.380 | 0.236 | 0.107 |
| Location | 0.433 | 0.082 | <0.001 |
| Residual variances | 0.115 | 0.026 | <0.001 |
| Intercept (HarmsT3) | -0.042 | 0.093 | 0.649 |
| Dispersion (HarmsT3) | 3.563 | 0.207 | <0.001 |

SECONDARY OUTCOMES

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3 A range of secondary outcomes were also examined within the study. These included the
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5 primary outcomes assessed at T2:
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10 *Heavy episodic drinking (HED) (T2):* Self-reported alcohol use defined as self-reported
11 consumption of >5 drinks, assessed at +24 months (T2) from baseline. This was dichotomised
12 at none/one or more occasions. This outcome was assessed via a two level random intercepts
13 logistic regression model. Around 12.4% of respondents reported HED at T2 using this
14 measure. In the intervention arm HED was reported by 10.9% (N=573) and in the control arm
15 by 13.9% (N=722).
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26 *Alcohol related harms (T2):* The number of self-reported harms (harms caused by own
27 drinking) assessed at +24 months (T2) from baseline. Items included harms such as getting into
28 a physical fight or being sick after drinking. The outcome was a count of the number of discrete
29 harms reported (0-16) and was assessed by a two level random intercepts negative binomial
30 model. In the intervention arm 74.3% reported no drinking harms, while in the control arm
31 71.5% reported no harms.
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42 In addition, a number of secondary outcomes at T3 and T2 were also examined, including:
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47 *Lifetime drinking (T3):* Whether the pupils had ever consumed a full drink of alcohol at +33
48 months (T3) (two level random intercepts logistic regression model).
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53 *Last year drinking (T3):* Whether the pupils had consumed a full drink of alcohol in the last
54 year, assessed at +33 months (T3) (two level random intercepts logistic regression model).
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3 *Last month Drinking (T3)*: Whether the pupils had consumed a full drink of alcohol in the last
4 month, assessed at +33 months (T3) (two level random intercepts logistic regression model).
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10 *Harm from others (T3 and T2)*: The number of self-reported harms experienced that were the
11 result of other people's drinking, assessed at both +33 months (T3) and +24 months (T2) from
12 baseline (two level random intercepts negative binomial models). Harms included being hit or
13 having property damaged by someone who had been drinking.
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21 *Age of onset (T3 and T2)*: Self-reported age at which respondent first consumed a full drink,
22 assessed at both +33 months (T3) and +24 months (T2) from baseline (two level random
23 intercepts Cox regression model).
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31 *Unsupervised drinking (T3 and T2)*: Whether the pupils were permitted, by their parents(s), to
32 consume alcohol (with small group of friends or at parties) with no adult present, assessed at
33 both +33 months (T3) and +24 months (T2) from baseline (two level random intercepts logistic
34 regression model).
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42 *Number of drinks consumed (T3 and T2)*: Pupils were asked whether they usually drank from
43 a range of different alcohol drinks (beer, alcopops, spirits cider, wine, *Buckfast* [a popular brand
44 of fortified wine, with caffeine], others) and if so, how much did they usually drink. The values
45 for each drink were summed together to give a total. As the underlying items continued
46 decimals the total value was multiplied by 10 to create whole numbers.
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56 The secondary outcome analysis also included covariates at level 1 (individual) and level 2
57 (school) where appropriate:
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5 The models use for the secondary outcome were similar to those employed in the primary
6 outcome analysis with a single level one covariate, and the treatment indicator and stratification
7 variables used in the randomisation as level two covariates.
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14 **Level 1 covariate**

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16 *Relevant baseline drinking variable (T0):* For each outcome, the corresponding baseline
17 observations were included in the model. Mean imputation was used to impute values for those
18 respondents who were missing on this variable. The only model not to include a baseline
19 covariate was age of onset.
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28 **Level 2 covariates**

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30 *Treatment Arm:* This was a binary covariate in which schools in the control arm were coded 0
31 and schools in the intervention arm were coded 1.
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38 *Free school meals (Randomisation stratification factor):* Schools were classified into three
39 groups based on free school meal provision. The allocation was based on a tertile split based
40 on information provided by head teachers on the proportion of pupils in receipt of free school
41 meals: *Low* Free School Meal Provision (0-15.4%), *Moderate* Free School Meal Provision
42 (15.5-30.4%), *High* Free School Meal Provision (30.5% and above).
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51 *School type (Randomisation stratification factor):* Given the larger number of schools in
52 Northern Ireland, an additional stratification factor was used in the randomisation. This was
53 school type (all boys' school/ all girls' school/coeducation school). Schools in
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Glasgow/Inverclyde were all assigned to the co-education type. This indicator was used represented by two dummy variables (co-education was the comparison category).

Location: A dummy variable was generated to indicate the location of the schools (Northern Ireland/Scotland).

Results from the analysis of secondary outcomes

Table S3 presents the random intercept models for the primary outcomes at +24 months. The baseline measures were significant, as was location. For the HED outcomes both free school meals (tertile split) and school type were significant. The intervention arm was significant at a 0.05 level ($\beta=-0.241$; $p=0.041$). However, it failed to reach the much stricter threshold used in the primary analysis (0.025). It should be noted that the HED indicator used at +33 months, and as specified in the DAP, was different that that used at +24 months. In particular, this measure did not use gender specific splits, referred to drinks rather than units, and did not provide any visual guides to help with the estimation of amount consumed. This suggests that the significant intervention effect may have been partly dependent on the precision of the measurement instrument used to collect the primary outcome data. The age at which differences in HED were assessed may have been important when assessing intervention outcomes.

Table S3. Secondary analysis: primary outcomes at +24 months

| | Estimate | S.E. | OR | P value |
|---|----------|-------|-------|---------|
| HED T2 (ITT CC population, logistic model) | | | | |
| <i>Within level</i> | | | | |
| Baseline HED | 1.891 | 0.101 | 6.623 | <0.001 |
| <i>Between Level</i> | | | | |
| Treatment Arm | -0.241 | 0.118 | | 0.041 |
| Free School Meals (tertile) | 0.308 | 0.079 | | <0.001 |

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|--|-----------------------------|--------|-------|--------|
| School Type | | | | |
| | <i>Boys School Dummy</i> | -0.708 | 0.297 | 0.02 |
| | <i>Girls School Dummy</i> | -0.608 | 0.186 | 0.001 |
| | Location | 0.732 | 0.134 | <0.001 |
| | Residual variance | 0.214 | 0.047 | <0.001 |
| | Threshold (BngT2\$1) | 2.698 | 0.144 | <0.001 |
| Harms to Self T2 (ITT CC population, negative binomial model) | | | | |
| <i>Within level</i> | | | | |
| | Baseline Harms drinking | 0.297 | 0.016 | <0.001 |
| <i>Between Level</i> | | | | |
| | Treatment Arm | -0.144 | 0.118 | 0.22 |
| | Free School Meals (tertile) | 0.162 | 0.086 | 0.06 |
| School Type | | | | |
| | <i>Boys School Dummy</i> | -0.247 | 0.302 | 0.42 |
| | <i>Girls School Dummy</i> | -0.246 | 0.200 | 0.22 |
| | Location | 0.716 | 0.132 | <0.001 |
| | Residual variance | 0.267 | 0.054 | <0.001 |
| | Intercepts (SHarmsT2) | -0.779 | 0.133 | <0.001 |
| | Dispersion | 4.478 | 0.304 | <0.001 |

Table S4 presents the outcome models for the additional secondary outcomes assessed at T3.

The treatment indicator was not significant in any of these models.

Table S4. Secondary outcomes at +33 months

| | Estimate | S.E. | OR | P value | |
|---|-----------------------------|--------|-------|---------|--------|
| Lifetime drinking T3 (ITT CC population, logistic model) | | | | | |
| <i>Within level</i> | | | | | |
| | Baseline HED | 2.070 | 0.081 | 7.922 | <0.001 |
| <i>Between Level</i> | | | | | |
| | Treatment Arm | -0.125 | 0.102 | | 0.22 |
| | Free School Meals (tertile) | 0.040 | 0.070 | | 0.57 |
| School Type | | | | | |
| | <i>Boys School Dummy</i> | -0.182 | 0.209 | | 0.384 |
| | <i>Girls School Dummy</i> | -0.501 | 0.233 | | 0.031 |
| | Location | 0.597 | 0.113 | | <0.001 |
| | Residual variance | 0.209 | 0.035 | | <0.001 |
| | Threshold (LifeT3\$1) | 0.419 | 0.114 | | <0.001 |

Table S4. Secondary outcomes at +33 months (cont.)

| | Estimate | S.E. | OR | P value | |
|--|-----------------------------|--------|-------|---------|--------|
| Last year drinking T3 (ITT CC population, logistic model) | | | | | |
| <i>Within level</i> | | | | | |
| | Baseline Last year drinking | 1.822 | 0.086 | 6.187 | <0.001 |
| <i>Between Level</i> | | | | | |
| | Treatment Arm | -0.126 | 0.096 | | 0.19 |
| | Free School Meals (tertile) | 0.011 | 0.065 | | 0.87 |

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| 3 | School Type | | | | |
| 4 | <i>Boys School Dummy</i> | -0.176 | 0.211 | 0.40 | |
| 5 | <i>Girls School Dummy</i> | -0.401 | 0.229 | 0.08 | |
| 6 | Location | 0.615 | 0.105 | <0.001 | |
| 7 | Residual variances | 0.177 | 0.032 | <0.001 | |
| 8 | Threshold (LYearT3\$1) | 0.485 | 0.103 | <0.001 | |
| 9 | Last month drinking T3 (ITT CC population, logistic model) | | | | |
| 10 | <i>Within level</i> | | | | |
| 11 | Baseline Last month drinking | 1.329 | 0.114 | 3.779 | <0.001 |
| 12 | <i>Between Level</i> | | | | |
| 13 | Treatment Arm | -0.149 | 0.094 | | 0.11 |
| 14 | Free School Meals (tertile) | 0.114 | 0.069 | | 0.10 |
| 15 | School Type | | | | |
| 16 | <i>Boys School Dummy</i> | -0.333 | 0.213 | | 0.12 |
| 17 | <i>Girls School Dummy</i> | -0.330 | 0.237 | | 0.16 |
| 18 | Location | 0.381 | 0.104 | | <0.001 |
| 19 | Residual variances | 0.148 | 0.028 | | <0.001 |
| 20 | Threshold (LMonthT3\$1) | 1.459 | 0.102 | | <0.001 |
| 21 | Harms from others drinking T3 (ITT CC population, Neg Bin model) | | | | |
| 22 | <i>Within level</i> | | | | |
| 23 | Baseline Harms (others) | 0.330 | 0.016 | | <0.001 |
| 24 | <i>Between Level</i> | | | | |
| 25 | Treatment Arm | 0.000 | 0.057 | | 0.10 |
| 26 | Free School Meals (tertile) | 0.077 | 0.042 | | 0.07 |
| 27 | School Type | | | | |
| 28 | <i>Boys School Dummy</i> | 0.117 | 0.116 | | 0.31 |
| 29 | <i>Girls School Dummy</i> | -0.070 | 0.172 | | 0.68 |
| 30 | Location | 0.167 | 0.063 | | 0.01 |
| 31 | Residual variance | 0.050 | 0.014 | | <0.001 |
| 32 | Dispersion | 1.301 | 0.071 | | <0.001 |
| 33 | Intercept | -0.733 | 0.061 | | <0.001 |
| 34 | Age of onset T3 (ITT CC population, Cox regression model) | | | | |
| 35 | <i>Between Level</i> | | | | |
| 36 | Treatment Arm | -0.095 | 0.067 | | 0.16 |
| 37 | Free School Meals (tertile) | 0.054 | 0.047 | | 0.25 |
| 38 | School Type | | | | |
| 39 | <i>Boys School Dummy</i> | -0.299 | 0.146 | | 0.04 |
| 40 | <i>Girls School Dummy</i> | -0.407 | 0.145 | | 0.01 |
| 41 | Location | 0.344 | 0.075 | | <0.001 |
| 42 | Residual variance | 0.097 | 0.017 | | <0.001 |

Table S4. Secondary outcomes at +33 months (cont.)

| | Estimate | S.E. | OR | P value | |
|----|--|--------|-------|---------|--------|
| 54 | | | | | |
| 55 | Unsupervised drinking T3 (ITT CC population Logistic model) | | | | |
| 56 | <i>Within level</i> | | | | |
| 57 | Baseline unsupervised drinking | 1.782 | 0.091 | 5.940 | <0.001 |
| 58 | <i>Between Level</i> | | | | |
| 59 | Treatment Arm | -0.142 | 0.092 | | 0.123 |
| 60 | Free School Meals (tertile) | 0.128 | 0.067 | | 0.058 |

| | | | |
|---|--------|-------|--------|
| School Type | | | |
| <i>Boys School Dummy</i> | 0.002 | 0.207 | 0.992 |
| <i>Girls School Dummy</i> | -0.236 | 0.236 | 0.318 |
| Location | 0.564 | 0.102 | <0.001 |
| Residual variance | 0.148 | 0.029 | <0.001 |
| Threshold (Unsuper\$1) | 0.148 | 0.029 | <0.001 |
| Number of drinks T3 (ITT CC population NB model) | | | |
| <i>Within level</i> | | | |
| Baseline number of drinks | 0.126 | 0.009 | <0.001 |
| <i>Between Level</i> | | | |
| Treatment Arm | -0.078 | 0.075 | 0.297 |
| Free School Meals (tertile) | 0.123 | 0.048 | 0.011 |
| School Type | | | |
| <i>Boys School Dummy</i> | -0.277 | 0.181 | 0.127 |
| <i>Girls School Dummy</i> | -0.167 | 0.177 | 0.346 |
| Location | 0.363 | 0.075 | <0.001 |
| Residual variances | 0.073 | 0.020 | <0.001 |
| Intercept (NumDrkT3) | 3.521 | 0.082 | <0.001 |
| Dispersion (NumDrkT3) | 5.371 | 0.306 | <0.001 |

Note: The logistic regression multilevel models were estimated using a logit link function and the MLR estimator. The Cox regression model uses a non-parametric baseline hazard function and a profile likelihood estimation method

Table S5 presents the models for the secondary outcomes assessed at T2. Again, the treatment indicator was not significant in any of these models.

Table S5. Secondary outcomes at +24 months

| | Estimate | S.E. | OR | P value |
|---|----------|-------|----|---------|
| Harms from others drinking T2 (ITT CC population, Neg Bin model) | | | | |
| <i>Within level</i> | | | | |
| Baseline Harms (others) | 0.421 | 0.017 | | <0.001 |
| <i>Between Level</i> | | | | |
| Treatment Arm | -0.058 | 0.060 | | 0.33 |
| Free School Meals (tertile) | 0.132 | 0.044 | | 0.003 |
| School Type | | | | |
| <i>Boys School Dummy</i> | 0.144 | 0.108 | | 0.18 |
| <i>Girls School Dummy</i> | 0.075 | 0.119 | | 0.53 |
| Location | 0.255 | 0.071 | | <0.001 |
| Residual variance | 0.058 | 0.011 | | <0.001 |
| Dispersion | 1.032 | 0.078 | | <0.001 |
| Intercept | -1.079 | 0.069 | | <0.001 |

Table S5. Secondary outcomes at +24 months

| | | | | |
|--|--------|-------|--|-------|
| Age of onset T2 (ITT CC population, Cox regression model) | | | | |
| <i>Between Level</i> | | | | |
| Treatment Arm | -0.055 | 0.074 | | 0.46 |
| Free School Meals (tertile) | 0.084 | 0.048 | | 0.08 |
| School Type | | | | |
| <i>Boys School Dummy</i> | -0.528 | 0.197 | | 0.007 |

| | | | | |
|---|--------------------------------|--------|-------|--------------|
| | <i>Girls School Dummy</i> | -0.453 | 0.169 | 0.007 |
| 4 | Location | 0.408 | 0.083 | <0.001 |
| 5 | Residual variance | 0.176 | 0.028 | <0.01 |
| Unsupervised drinking T2 (ITT CC population, Logistic model) | | | | |
| <i>Within level</i> | | | | |
| 8 | Baseline unsupervised drinking | 2.114 | 0.097 | 8.285 <0.001 |
| <i>Between Level</i> | | | | |
| 10 | Treatment Arm | -0.087 | 0.100 | 0.39 |
| 11 | Free School Meals (tertile) | 0.166 | 0.066 | 0.01 |
| School Type | | | | |
| 13 | <i>Boys School Dummy</i> | -0.306 | 0.217 | 0.16 |
| 14 | <i>Girls School Dummy</i> | -0.207 | 0.135 | 0.12 |
| 15 | Location | 0.669 | 0.112 | <0.001 |
| 16 | Residual variance | 0.170 | 0.038 | <0.001 |
| 17 | Threshold (Unsuper\$1) | 1.883 | 0.118 | <0.001 |
| Number of drinks T2 (ITT CC population, NB model) | | | | |
| <i>Within level</i> | | | | |
| 19 | Baseline unsupervised | 0.170 | 0.013 | <0.001 |
| <i>Between Level</i> | | | | |
| 21 | Treatment Arm | -0.088 | 0.096 | 0.36 |
| 22 | Free School Meals (tertile) | 0.125 | 0.068 | 0.07 |
| School Type | | | | |
| 24 | <i>Boys School Dummy</i> | -0.574 | 0.259 | 0.03 |
| 25 | <i>Girls School Dummy</i> | -0.181 | 0.147 | 0.22 |
| 26 | Location | 0.583 | 0.105 | <0.001 |
| 27 | Residual variances | 0.153 | 0.035 | <0.001 |
| 28 | Intercept (NumDrkT2) | 2.836 | 0.106 | <0.001 |
| 29 | Dispersion (NumDrkT2) | 5.671 | 0.340 | <0.001 |

Note: The logistic regression multilevel models were estimated using a logit link function and the MLR estimator. The Cox regression model uses a non-parametric baseline hazard function and a profile likelihood estimation method

Subgroup analyses

To explore differential treatment effects on the primary and secondary outcome measures, pre-specified interaction terms were fitted between trial arm and baseline measures thought to predict the effect of treatment. These were:

- Age, in months, of pupil at baseline;
- Gender;
- Socioeconomic status (using the proportion of free school meals indicator);
- Alcohol use behaviour at baseline – ever use, last year use, age of onset, and context of use (abstainer/supervised/unsupervised);
- and in NI, a Grammar/Secondary school analysis.

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6 Both the relevant covariate and interaction term were included in the model as a level 1
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8 (within level) covariates. In all the subgroup analysis models estimated the corresponding
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10 interaction terms were all non-significant.
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Table S1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

| Section/Topic | Item No | Standard Checklist item | Extension for cluster designs | Page No * |
|----------------------------------|---------|--|---|-------------|
| Title and abstract | | | | |
| | 1a | Identification as a randomised trial in the title | Identification as a cluster randomised trial in the title | 1 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) ^{1,2} | See table 2 | 2 |
| Introduction | | | | 4 |
| Background and objectives | 2a | Scientific background and explanation of rationale | Rationale for using a cluster design | 6 |
| | 2b | Specific objectives or hypotheses | Whether objectives pertain to the the cluster level, the individual participant level or both | 5, 11 |
| Methods | | | | 6 |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | Definition of cluster and description of how the design features apply to the clusters | 6 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | | N/A |
| Participants | 4a | Eligibility criteria for participants | Eligibility criteria for clusters | 6-7 |
| | 4b | Settings and locations where the data were collected | | 6 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Whether interventions pertain to the cluster level, the individual participant level or both | 8 & Table 1 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and | Whether outcome measures pertain to the cluster level, the individual participant level or both | 11 |

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| | | when they were assessed | | |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | | 12 |
| Sample size | 7a | How sample size was determined | Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty | 12 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | | N/A |
| Randomisation: | | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | | 7 |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Details of stratification or matching if used | 7 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both | 7 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Replace by 10a, 10b and 10c | 7 |
| | 10a | | Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions | 6 |
| | 10b | | Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete | 7 |

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| | | | enumeration, random sampling) | |
| | 10c | | From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation | 7 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | | 7-8 |
| | 11b | If relevant, description of the similarity of interventions | | 11 |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | How clustering was taken into account | 12 |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | | 14 |
| Results | | | | 15 |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome | 15 & Figure 1 |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | For each group, losses and exclusions for both clusters and individual cluster members | 15 & Figure 1 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | | 11 |
| | 14b | Why the trial ended or was stopped | | 16 |
| Baseline data | 15 | A table showing baseline demographic and clinical | Baseline characteristics for the individual and cluster levels as | 15 & Table 2 |

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| | | characteristics for each group | applicable for each group | |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | For each group, number of clusters included in each analysis | Table 2 |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome | 18 |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | | 18-19 |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | | 20 & online supplementary material |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms ³) | | 15 |
| Discussion | | | | 20 |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | | 21-22 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | Generalisability to clusters and/or individual participants (as relevant) | 23 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | | 23-24 |
| Other information | | | | |
| Registration | 23 | Registration number and | | 14 |

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| | | name of trial registry | |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | 6 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 24 and information included as part of journal submission process |

* Note: page numbers optional depending on journal requirements

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Table 2: Extension of CONSORT for abstracts^{1,2} to reports of cluster randomised trials

| Item | Standard Checklist item | Extension for cluster trials |
|---------------------------|---|--|
| Title | Identification of study as randomised | Identification of study as cluster randomised |
| Trial design | Description of the trial design (e.g. parallel, cluster, non-inferiority) | |
| Methods | | |
| Participants | Eligibility criteria for participants and the settings where the data were collected | Eligibility criteria for clusters |
| Interventions | Interventions intended for each group | |
| Objective | Specific objective or hypothesis | Whether objective or hypothesis pertains to the cluster level, the individual participant level or both |
| Outcome | Clearly defined primary outcome for this report | Whether the primary outcome pertains to the cluster level, the individual participant level or both |
| Randomization | How participants were allocated to interventions | How clusters were allocated to interventions |
| Blinding (masking) | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | |
| Results | | |
| Numbers randomized | Number of participants randomized to each group | Number of clusters randomized to each group |
| Recruitment | Trial status ¹ | |
| Numbers analysed | Number of participants analysed in each group | Number of clusters analysed in each group |
| Outcome | For the primary outcome, a result for each group and the estimated effect size and its precision | Results at the cluster or individual participant level as applicable for each primary outcome |
| Harms | Important adverse events or side effects | |
| Conclusions | General interpretation of the results | |
| Trial registration | Registration number and name of trial register | |
| Funding | Source of funding | |

¹ Relevant to Conference Abstracts

REFERENCES

- 1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283
- 2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20
- 3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.