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Effects of the Learning Together intervention on bullying and aggression in English secondary schools (INCLUSIVE): a cluster randomised controlled trial



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Summary

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See [Comment](#) page 2416

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Background Bullying, aggression, and violence among children and young people are some of the most consequential public mental health problems. We tested the Learning Together intervention, which involved students in efforts to modify their school environment using restorative practice and by developing social and emotional skills.

Methods We did a cluster randomised trial, with economic and process evaluations, of the Learning Together intervention compared with standard practice (controls) over 3 years in secondary schools in south-east England. Learning Together consisted of staff training in restorative practice; convening and facilitating a school action group; and a student social and emotional skills curriculum. Primary outcomes were self-reported experience of bullying victimisation (Gatehouse Bullying Scale; GBS) and perpetration of aggression (Edinburgh Study of Youth Transitions and Crime (ESYTC) school misbehaviour subscale) measured at 36 months. We analysed data using intention-to-treat longitudinal mixed-effects models. This trial was registered with the ISRCTN registry (10751359).

Findings We included 40 schools (20 in each group); no schools withdrew. 6667 (93·6%) of 7121 students participated at baseline and 5960 (83·3%) of 7154 at 36 months. Mean GBS bullying score at 36 months was 0·34 (SE 0·02) in the control group versus 0·29 (SE 0·02) in the intervention group, with a significant adjusted mean difference (–0·03, 95% CI –0·06 to –0·001; adjusted effect size –0·08). Mean ESYTC score at 36 months was 4·33 (SE 0·20) in the control group versus 4·04 (0·21) in the intervention group, with no evidence of a difference between groups (adjusted difference –0·13, 95% CI –0·43 to 0·18; adjusted effect size –0·03). Costs were an additional £58 per pupil in intervention schools than in control schools.

Interpretation Learning Together had small but significant effects on bullying, which could be important for public health, but no effect on aggression. Interventions to promote student health by modifying the whole-school environment are likely to be one of the most feasible and efficient ways of addressing closely related risk and health outcomes in children and young people.

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Introduction

Bullying, aggression, and violence among children and young people are among the most consequential public mental health problems.^{1,2} WHO defines bullying as the intentional use of physical or psychological force against others,³ and violence as the intentional use of physical force against oneself or others.⁴ Aggression consists of hostile or destructive behaviour, and is a common part of bullying or violence. Bullying is more prevalent among British young people⁵ than in other western European countries,⁶ with cyber-bullying becoming one of the most common forms.⁷ Childhood exposure to bullying and violence results in multiple physical and mental health harms in childhood and in adult life,^{8–14} as well as lower educational attainment.¹⁵ Prevention of bullying and violence is therefore a major priority for public health and education systems internationally,^{2,16} with schools a

key focus of initiatives to improve young people's mental health and wellbeing.¹⁷ A challenge is to address these inter-related behaviours using single coherent interventions rather than overburdening busy schools with multiple interventions.

We developed and piloted a school-based intervention based on the three most promising approaches to reducing bullying and other health risks. The first are whole-school interventions aiming to modify overall school policies and systems rather than merely to deliver classroom-based lessons addressing bullying or other outcomes.¹⁸ A key element of many such interventions is to increase student engagement with school as a social determinant of health, particularly for the most socially disadvantaged students.^{19,20} Systematic reviews and trials suggest that such approaches reduce risk behaviours including violence and anti-social behaviour^{21,22} and

Research in context

Evidence before this study

Reviews have shown the pervasive effect of bullying in adolescence on contemporary and later health, wellbeing, and social functioning. Systematic reviews indicate that whole-school interventions are among the most promising approaches to the promotion of young people's health, and that these are effective in reducing bullying victimisation. Restorative practice is increasingly used in schools to address bullying and antisocial behaviour. We undertook a systematic review in January, 2018, of PubMed using the search terms (((("Schools"[Mesh]) AND "Randomized Controlled Trial" [Publication Type]) AND ("Bullying"[Majr]) OR "Aggression"[Majr])) AND restorative justice. We identified no published randomised trials or systematic reviews of restorative practice interventions in schools.

Added value of this study

We present the first evidence from a randomised trial that a whole-school intervention including restorative practice and

social and emotional learning elements, has positive effects on bullying; mental health and wellbeing; quality of life; smoking, alcohol and drug use; and police contact.

The Learning Together intervention is very low cost compared with other educational interventions and offers a coherent means of addressing clustered risks and health outcomes in schools.

Implications of all the available evidence

Interventions aiming to promote student health by modifying the whole-school environment can have effects of public health importance across a broad range of important outcomes in young people. The inclusion of restorative practice within such interventions can reduce bullying among all young people and reduce aggressive behaviour in those with high baseline aggression.

bullying victimisation.¹⁸ The large SEHER trial²³ in Bihar, India, showed that such interventions can be effective in resource-poor settings.

The second promising approach is based on restorative practice, which aims to prevent or resolve conflicts between students or between staff and students to prevent further harms.²⁴ It enables victims to communicate to perpetrators the effects of the harm, and for perpetrators to acknowledge and amend their behaviour to avoid further harms. Restorative practice can involve primary prevention of incidents (such as so called circle-time, in which students are brought together with their teacher to discuss their feelings, identify problems, and maintain good relationships) or secondary prevention to resolve incidents (such as conferencing, bringing together parties to a conflict and, when necessary, external agencies, to reflect on more serious incidents and develop strategies to avoid future harms). Restorative practice is increasingly used within schools in the UK and internationally to address bullying and antisocial behaviour, with encouraging results from non-randomised evaluations.^{16,25} However, there have been no randomised trials of restorative practice in schools.²⁶

The third is social and emotional education. Lessons to teach young people the skills needed to manage their emotions and relationships can enhance social relationships, improve mental health, and reduce bullying.²⁷

In 2014, we developed the Learning Together intervention,²⁸ which aimed to modify the school environment by using all three of these approaches to reduce bullying and aggression, and promote student health and wellbeing across various domains. A pilot trial²⁸ in eight schools showed that the intervention was feasible

and acceptable to participants. We then did the INCLUSIVE trial, a cluster-randomised controlled trial of Learning Together. We hypothesised that secondary schools using the intervention would have lower rates of self-reported bullying and perpetration of aggression, and improved student and staff secondary outcomes compared with control schools, and that Learning Together would be cost-effective compared with standard school practice. Here, we report student health and behaviour outcomes. Data on student educational outcomes and staff outcomes will be published when routine administrative data become available in 2019.

Methods

Study design and participants

We did a cluster-randomised controlled trial, along with process evaluation (an assessment of implementation, context, reach, and acceptability) and an economic assessment, in 40 secondary schools in southeast England between 2014 and 2017, with schools as the unit of allocation.²⁹ We included all students in the school at the end of year 7 (age 11–12 years) at baseline, with follow-up at 24 months and 36 months (end of year 10; age 14–15 years). There were no ineligibility criteria for students.

We enrolled mainstream secondary schools within the state education system that had a most recent school quality rating by the Ofsted (the national education inspectorate in the UK) of: "requires improvement", "satisfactory", "good", or "outstanding". We excluded schools with an "inadequate/poor" rating because such schools are subject to special measures, which were likely to impede delivery of the intervention. We identified and contacted all eligible schools in Greater London and surrounding counties between March, and June, 2014.

The protocol was amended during the trial to refine the methods. All amendments were approved by the independent study steering committee. The only change to trial outcomes was adding a measure of bullying perpetration as a secondary outcome. All refinements were completed before collection of the 36-month surveys and before trial analyses.

The trial was approved by the University College London ethics committee (ref 5248/001). Written, informed consent was obtained from head teachers for random allocation and intervention, and from individual students, staff, and intervention facilitators for data collection. Information sheets and consent forms for student surveys were identical in intervention and control schools and did not refer to the intervention. Parents were informed about the study and could withdraw their children from research activities.

See Online for appendix

Randomisation and masking

We randomly allocated schools (1:1) to the intervention group (Learning Together) or the control group (standard practice) immediately after baseline surveys. We stratified randomisation by key school-level determinants of violence,³⁰ with data obtained from the Department for Education:³¹ (1) single sex versus mixed sex school; (2) school-level deprivation, as measured by the percentage of students eligible for free school meals (low or moderate 0–23%; high >23%; 23% is the 75th centile for England); and (3) student attainment in General Certificate of Secondary Education examinations normally sat by students aged 16 years, with a total score based on the best eight grades achieved by each student accounting for previous attainment at age 11 years (above and below median score of 1000 across English schools), a school-level measure of students' attainment.

Sequence allocation was generated by the Clinical Trials Unit at The London School of Hygiene & Tropical Medicine using Stata's `ralloc` command, and was concealed from schools and the wider evaluation and intervention teams. Allocation was communicated to the research team who then communicated it to schools and the intervention team.

Schools, the intervention team, and process and economic evaluators could not be masked to allocation status. However, fieldwork staff were masked to allocation as was the outcome research team lead (RMV), and staff who entered and analysed data.

Procedures

Baseline surveys were done between March and July, 2014; 24-month follow-up surveys were done in April to June, 2016; and 36-month follow-up surveys were done in April to June, 2017. Student self-reported data were collected using paper questionnaires, which students completed in classrooms under examination conditions facilitated by trained researchers with teachers present but unable to read student responses. Questionnaires were

double-entered by trained personnel. Questionnaires with additional text, regardless of content, were scanned and password-protected scans were sent to the study team to assess serious adverse events and abuse requiring safeguarding interventions. Password-protected electronic data were securely transferred to the London School of Hygiene and Tropical Medicine and stored on secure servers.

Informed by prior theory,²⁰ the intervention aimed to enable young people to choose healthier behaviours by promoting their autonomy, motivation, and reasoning ability. These were to be promoted by increasing engagement with school via improving relationships between and among students and teachers, and between academic education and broader student development, as well as by reorienting school practices and organisation to centre on student needs (appendix p 4).

In the first year, all school staff were trained in restorative practices with in-depth training for selected staff from accredited providers over 3 days. Schools were provided with a manual to guide action group meetings of at least six staff and six students, held twice per term, to revise relevant school policies and coordinate the intervention. These groups ensured that local implementation of the intervention was appropriate for students, with scope for some locally decided actions. For the first 2 years, the groups who attended action group meetings were encouraged to discuss and take action by an external facilitator with school management experience. Schools were sent a report on local needs, derived from the student surveys, to inform decisions. They were also provided with lesson plans and slides to guide teachers' delivery of 5–10 h per year of lessons on social and emotional skills for students in years 8–10 (age 12–15 years). School staff delivered primary restorative practices using respectful language to challenge or support behaviour and circle time to build relationships, and secondary restorative practices involved some staff implementing restorative conferences to address more serious behaviour problems.

Schools randomised to the control group continued with their normal practices and received no additional input. The sample of schools happened to be spread over a wide geographical area and there were no intervention and control schools in close proximity. Head teachers and a few staff were aware that the school was participating in the INCLUSIVE trial but were not informed of the name or detailed contents of the intervention.

In line with the UK Medical Research Council guidance on complex interventions,³² we did a process evaluation assessing trial context and trial group fidelity in all schools. For trial context, we examined services and practices relating to bullying, discipline, and social and emotional skills education, and student participation in school policy in control schools to assess how these differed from the intervention. This assessment drew on interviews with one member of each control school's senior leadership team and two other members of staff

done in the first year of intervention, and interviews with a senior leadership team member in the third year.

We scored fidelity to the intervention in the first 2 years out of eight points for each school, assessing whether: at least five staff attended in-depth training; six action-group meetings occurred per year; policies and rules were reviewed; locally decided actions were implemented; members assessed that action groups had a good or very good range of members; members assessed that action groups were well or very well led; schools delivered at least 5 h or two modules each year; at least 85% of staff reported that if there was trouble at the school, staff responded by talking to those involved to help them get on better. We assessed fidelity in the third year using a narrower range of data because the research teams had less access to schools. Schools were scored out of four on whether: six action groups were convened; local decisions were implemented; schools delivered at least 5 h or at least two modules; and at least 85% of staff reported that if there was trouble at the school, staff responded by talking to those involved to help them get on better. The appendix (p 16–29) provides additional data on the process evaluation.

Process evaluation interviews were done annually in each intervention school with two action group members. They used purposive sampling to involve participants with diversity in terms of characteristics thought important for exploring implementation.³³ Six intervention schools were chosen (encompassing a range of percentages of students entitled to free school meals, types of state school, and facilitator and school responsiveness to intervention activities) as case studies for more in-depth process evaluation involving two focus groups with students and one with staff each year. The six were selected to encompass variation by percentage of students entitled to free school meals, type of state school, facilitator and school responsiveness to intervention activities rated by facilitators after three months

For the economic evaluation, we used a cost-consequence analysis including all main outcomes and evaluated incremental effects at 24 months and 36 months since randomisation. Costs included use of education, police, and NHS resources (appendix p 31).³⁴ We collected data on the costs of delivering the intervention from the invoices for facilitators and trainers and data from the process evaluation on school staff time requirements. We determined the costs of staff time taken to deal with bullying through the staff survey questionnaire, and the costs of NHS and police resource data through the student survey questionnaires and valued them accordingly.

We defined serious adverse events as (1) any death, serious injury, or hospital admission in any student in a trial school that was reported to investigators; or (2) responses on study questionnaires that prompted significant concerns about mental health, sexual risk, or child safety, which were then communicated to the school.

Outcomes

The primary outcomes were self-reported experience of bullying victimisation and perpetration of aggression measured at 36 months. Outcome data were collected by a research team (led by RMV), independent of the intervention team (lead by CB).

We measured bullying victimisation using the Gatehouse Bullying Scale (GBS), a 12-item validated³⁵ self-reported measure of being subject to teasing, name-calling, rumours, being left out of things, and physical threats or actual violence from other students, including face-to-face and cyber-bullying, within the past 3 months. Students reported the frequency and upset related to each experience. Items are summed to make a total bullying score (higher represents more frequent, upsetting bullying).

We measured perpetration of aggressive behaviour using the Edinburgh Study of Youth Transitions and Crime (ESYTC) school misbehaviour subscale,³⁶ a 13-item scale measuring self-reported aggression towards students and teachers. Each item was coded from hardly ever or never; less than once a week; at least once a week; to most days. Items are summed to provide a total score; high scores indicate greater aggressive behaviour.

The secondary outcomes included GBS and ESYTC scores at 24 months. The other secondary outcomes assessed at 36 months were quality of life measured with the Paediatric Quality of Life Inventory,³⁷ version 4.0 (higher scores indicate better quality of life); wellbeing, measured with the validated Short Warwick-Edinburgh Mental Well-Being Scale³⁸ (higher scores indicate greater emotional wellbeing); psychological problems, measured with the Strengths and Difficulties Questionnaire³⁹ (a brief, validated instrument for detecting behavioural, emotional, and peer problems in children and adolescents; a higher score indicates greater problems); bullying perpetration, measured with the Modified Aggression Scale, Bullying Subscale⁴⁰ (used at follow-up only; higher scores indicated greater bullying); substance use, assessed using validated age-appropriate questions about cigarette smoking, alcohol use, and illicit drug use taken from national surveys;⁴¹ sexual risk behaviour⁴² (age of sexual debut and use of contraception at first sex; assessed only at follow-up); use of NHS health services (self-reported use of primary care, accident and emergency, or other service in the past 12 months); and contact with police (self-report of being stopped, reprimanded, or picked up by the police in the past 12 months).

Statistical analysis

We calculated that, using a conservative intraclass correlation coefficient⁴³ of 0.04 and an estimate of 150 students per school, a trial involving 20 schools per group would provide 90% power to identify an effect size of 0.25 SD with a 5% significance level. This difference is considered to represent a moderate size of effect and is

	Control group	Intervention group
School characteristics		
Number of schools	20	20
School sex mix		
Mixed	15 (75%)	15 (75%)
Girls only	3 (15%)	4 (20%)
Boys only	2 (10%)	1 (5%)
School type		
Voluntary	1 (5%)	3 (15%)
Community school	3 (15%)	2 (10%)
Academy (converter mainstream)	9 (45%)	10 (50%)
Academy (sponsor led)	3 (15%)	3 (15%)
Foundation school	4 (20%)	2 (10%)
Ofsted rating*		
Excellent	5 (25%)	6 (30%)
Good	13 (65%)	12 (60%)
Requires improvement	2 (10%)	2 (10%)
Mean value added score	1003 (24.8)	1004 (20.4)
Mean proportion of students on free school mean (%)	36 (18.0)	35 (22.0)
Mean school size	1122 (322.7)	1046 (323.3)
Mean IDAC1 score	0.26 (0.2)	0.24 (0.2)
Student characteristics		
Number of students	3347†	3320†
Mean age (years)	12 (0.4)	12 (0.4)
Sex		
Male	1639 (49.9%)	1464 (44.9%)
Female	1649 (50.2%)	1804 (55.2%)
Ethnicity		
White British	1391 (41.5%)	1221 (37.3%)
White other	291 (8.8%)	273 (8.3%)
Asian or Asian British	859 (25.9%)	786 (24.0%)
Black or Black British	384 (11.6%)	535 (16.4%)
Chinese or Chinese British	11 (0.3%)	35 (1.1%)
Mixed ethnicity	238 (7.2%)	224 (6.9%)
Other	140 (4.2%)	198 (6.1%)

(Table 1 continues in next column)

	Control group	Intervention group
(Continued from previous column)		
Religion		
None	983 (29.6%)	787 (24.0%)
Christian	1073 (32.3%)	1173 (35.8%)
Jewish	9 (0.3%)	13 (0.4%)
Muslim	878 (26.5%)	817 (24.9%)
Hindu	90 (2.7%)	176 (5.4%)
Sikh	71 (2.1%)	88 (2.7%)
Don't know	145 (4.4%)	126 (3.8%)
Other	73 (2.2%)	100 (3.1%)
Family structure		
Two parents	2393 (71.9%)	2369 (72.1%)
Single mothers	604 (18.2%)	626 (19.0%)
Single fathers	37 (1.1%)	56 (1.7%)
Reconstituted	246 (7.4%)	204 (6.2%)
Other	48 (1.4%)	33 (1.0%)
At least one parent in work		
No	298 (8.7%)	233 (7.2%)
Yes	2437 (74.0%)	2381 (73.4%)
Don't know	566 (11.2%)	632 (19.5%)
Housing tenure		
Renting from council or housing association	474 (14.4%)	559 (17.3%)
Renting from a landlord	391 (11.9%)	396 (12.2%)
Owned by family	1451 (44.1%)	1273 (39.3%)
Other	62 (1.9%)	59 (1.8%)
Don't know	912 (27.7%)	951 (29.4%)
Mean family affluence scale	6 (1.8)	6 (1.8)

Data are n (%) or mean (SD) unless otherwise stated. *One control school did not have an Ofsted rating. †The number of students who responded at this survey; actual number of responses to each question varies, but item non-response was similar in each group.

Table 1: Baseline characteristics

in line with effect sizes in previous studies.⁴⁴ We therefore planned to include roughly 6000 students.

The primary analysis of outcomes was by intention to treat, including all randomly assigned schools and students. We analysed each measure using a separate mixed model with the outcomes from each timepoint treated as a repeated measures. Fixed effects of group (intervention vs control), time (baseline, 24 months, 36 months), and the interaction between treatment and time were specified, and the estimated baseline measures were constrained to be identical in the two groups of the trial. This approach is equivalent to adjusting for baseline and permitting the relationship between baseline and follow-up scores to differ at each timepoint, but offers the additional advantage that the data from all participants contribute to the analysis, even when there were missing

data at follow-up. Details of missing data are shown in the appendix (p 35). We used random effects for school and participants to allow for correlations within schools and repeated measures within participants. Statistical significance for these analyses was taken at the 5% level ($p < 0.05$). We did analyses adjusted only for baseline measures of the outcomes and in the primary analysis adjusted for baseline measures of outcomes, sex, ethnicity, socioeconomic status, and school-level stratification factors.

For the two primary outcomes, we used mixed linear regression models with random effects at the participant and school levels to estimate the mean difference in GBS and ESYTC scores between the two arms of the trial. We restricted formal testing to the prespecified of secondary outcomes, and we used appropriate multilevel models to examine the effect of the intervention. For continuous outcomes, we calculated unadjusted and adjusted mean differences with 95% CIs and adjusted effect sizes (standardised mean difference). For binary and ordinal outcomes, we calculated unadjusted and adjusted odds

ratios. Additionally, we also calculated adjusted risk differences for binary outcomes. We assessed differential effects of the intervention on the primary and secondary outcomes by subgroup using likelihood ratio tests for the treatment by subgroup interaction terms. We estimated the effects in the different subgroups directly from the regression model with the interaction term included.

We did four subgroup analyses: (1) by sex; (2) by socioeconomic status, measured using the Health Behaviours in School-aged Children Family Affluence Scale (<5 for low vs ≥6 for high);⁴⁵ (3) baseline bullying experience based on GBS (high, defined as at least weekly experience of bullying or being upset by it vs medium or low, defined as less than weekly experience of bullying and not being upset by it); and (4) baseline behaviour problems based on the ESYTC (>0 for high vs 0 for low).

For the process evaluation of trial context and intervention fidelity, we used thematic content analysis for qualitative data and descriptive statistics for quantitative data. For the economic analysis we used general linear mixed regression models that allowed for clustering of students within schools, and including school as a random effect variable.

The trial is registered with ISRCTN (ISRCTN10751359).

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

6667 (93.6%) of 7121 registered students in the 40 participating schools provided data at baseline (3320 [94.4%] of 3516 in the intervention group vs 3347 [92.8%] of 3605 in the control group). Table 1 shows the baseline characteristics of schools and students, the characteristics of students at 24 months and 36 months are shown in the appendix (pp 6–7). The 40 participating schools did not differ significantly from 450 non-recruited schools in terms of size, population, deprivation, or gross or value-added attainment, but participating schools were more likely to have an Ofsted rating of good or outstanding (appendix p 4). All schools participated in the follow-up surveys at 24 months and 36 months; the numbers of students who completed the questionnaires at baseline, 24 months, and 36 months were similar in each group (figure). Student and school characteristics and outcomes at baseline were well balanced across arms. Primary and secondary outcomes at baseline are shown in the appendix (pp 8–9).

Mean GBS bullying score at 36 months was 0.34 (SE 0.02) in the control group versus 0.29 (SE 0.02) in the intervention group, with a significant adjusted mean difference (−0.03, 95% CI −0.06 to −0.001; adjusted effect size −0.08; table 2). Mean ESYTC score at

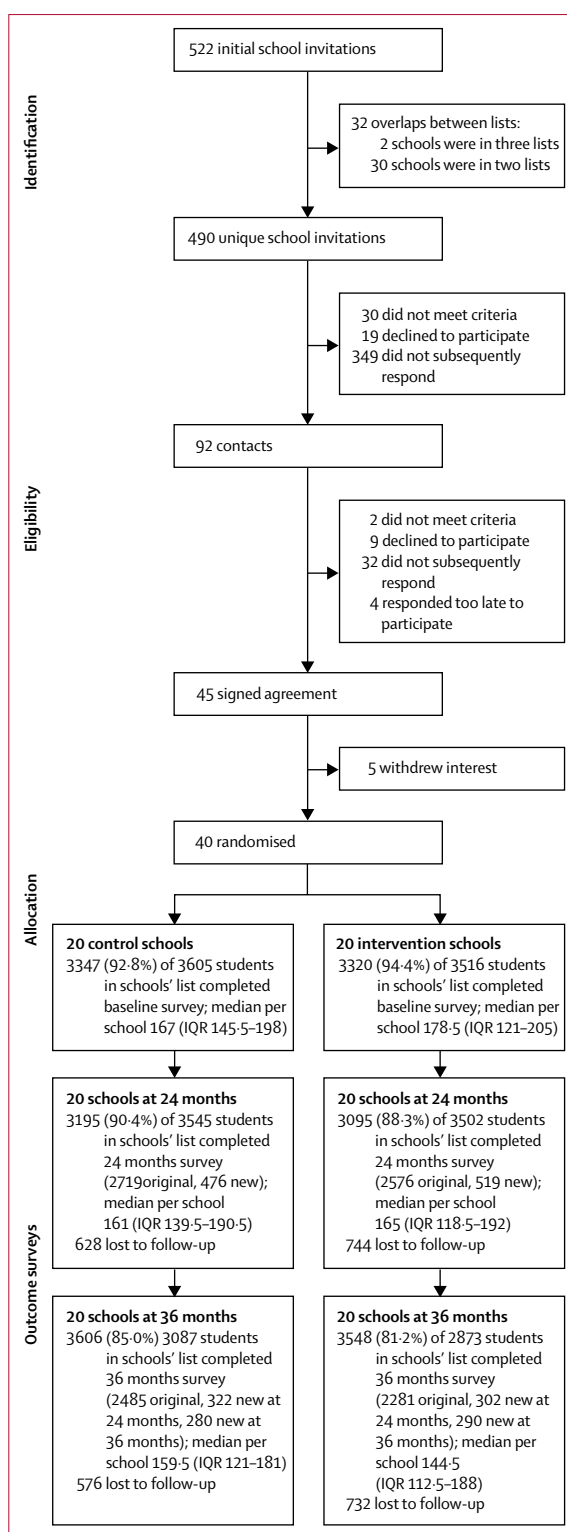


Figure: Trial profile

36 months was 4·33 (SE 0·20) in the control group versus 4·04 (0·21) in the intervention group, with no evidence of a difference between groups (adjusted difference −0·13, 95% CI −0·43 to 0·18; adjusted effect size −0·03).

With regards to the secondary outcomes, the GBS overall score and the ESYTC scores at 24 months were higher in the intervention groups than in the control groups, but we found no evidence of a significant difference (table 3). At 36 months, students in intervention schools had a higher

quality of life and psychological wellbeing and lower psychological difficulties than did students in control schools (table 3). There was also evidence that those in intervention schools had lower emotional, conduct, hyperactivity, and peer problems (table 3).

Students in intervention schools also had lower odds of having ever smoked regularly, lower odds of having ever drunk alcohol, and lower odds of having ever been offered or tried illicit drugs (table 4). Among students in

	Control group (3087 students)*	Intervention group (2281 students)*	Unadjusted difference (95% CI)	p value	Adjusted difference (95% CI)	p value	Adjusted effect size
GBS overall score	0·34 (0·02)	0·29 (0·02)	−0·03 (−0·06 to −0·002)	0·0395	−0·03 (−0·06 to −0·001)	0·0441	−0·08
Teasing	0·55 (0·03)	0·47 (0·03)	−0·04 (−0·09 to 0·01)	..	−0·05 (−0·10 to 0·000)	..	−0·07
Rumours	0·37 (0·02)	0·31 (0·02)	−0·06 (−0·10 to −0·02)	..	−0·07 (−0·11 to −0·02)	..	−0·10
Deliberate exclusion	0·24 (0·01)	0·22 (0·02)	−0·04 (−0·08 to −0·004)	..	−0·04 (−0·08 to 0·01)	..	−0·06
Threatened or hurt	0·21 (0·02)	0·18 (0·02)	0·01 (−0·02 to 0·05)	..	0·01 (−0·03 to 0·05)	..	0·02
ESYTC overall score	4·33 (0·20)	4·04 (0·21)	−0·07 (−0·38 to 0·25)	0·6820	−0·13 (−0·43 to 0·18)	0·4199	−0·03

Data are mean (SE) unless otherwise stated. GBS=Gatehouse Bullying Scale. ESYTC=Edinburgh Study of Youth Transitions and Crime. *Shows the number of students who responded at this survey; actual number of responses to each question varied, but non-response for each item was similar across arms.

Table 2: Primary outcomes at 36 months

	Control group (mean, SE)	Intervention group (mean, SE)	Unadjusted difference (95% CI)	p value	Adjusted difference (95% CI)	p value	Adjusted effect size
24 months	3195 students*	3095 students*
GBS overall score	0·42 (0·02)	0·37 (0·02)	−0·02 (−0·05 to 0·01)	0·2198	−0·02 (−0·05 to 0·01)	0·1581	−0·05
Teasing	0·66 (0·03)	0·59 (0·03)	−0·02 (−0·07 to 0·03)	..	−0·03 (−0·08 to 0·01)	..	−0·05
Rumours	0·44 (0·02)	0·41 (0·02)	−0·02 (−0·06 to 0·02)	..	−0·02 (−0·06 to 0·02)	..	−0·04
Deliberate exclusion	0·31 (0·02)	0·30 (0·02)	−0·03 (−0·07 to 0·01)	..	−0·03 (−0·07 to 0·01)	..	−0·05
Threatened or hurt	0·26 (0·02)	0·22 (0·02)	0·01 (−0·02 to 0·05)	..	0·01 (−0·03 to 0·04)	..	0·01
ESYTC overall score	4·24 (0·28)	3·96 (0·28)	−0·04 (−0·34 to 0·27)	0·8113	−0·06 (−0·35 to 0·24)	0·7206	−0·01
36 months	3087 students*	2281 students*
PedsQL overall score	78·82 (0·54)	80·65 (0·55)	1·16 (0·41 to 1·90)	0·0022	1·44 (0·70 to 2·17)	0·0001	0·14
Physical health	84·46 (0·61)	85·84 (0·63)	0·80 (−0·02 to 1·62)	..	1·05 (0·26 to 1·84)	..	0·09
Psychosocial health	75·75 (0·56)	77·87 (0·58)	1·46 (0·62 to 2·29)	..	1·71 (0·87 to 2·54)	..	0·15
Emotional functioning	71·41 (1·04)	73·38 (1·07)	1·52 (0·30 to 2·75)	..	2·08 (0·88 to 3·28)	..	0·12
Social functioning	87·16 (0·41)	88·57 (0·43)	0·98 (0·12 to 1·85)	..	1·04 (0·17 to 1·91)	..	0·08
School functioning	68·72 (0·70)	71·65 (0·72)	1·75 (0·72 to 2·79)	..	1·87 (0·83 to 2·91)	..	0·13
SDQ total difficulties score†	12·20 (0·18)	11·51 (0·19)	−0·51 (−0·80 to −0·22)	0·0005	−0·54 (−0·83 to −0·25)	0·0002	−0·14
Emotional problems	3·68 (0·12)	3·57 (0·12)	−0·13 (−0·25 to 0·001)	..	−0·14 (−0·26 to −0·02)	..	−0·08
Conduct problems	2·14 (0·05)	1·90 (0·05)	−0·14 (−0·24 to −0·05)	..	−0·17 (−0·26 to −0·07)	..	−0·13
Hyperactivity	4·48 (0·09)	4·27 (0·09)	−0·11 (−0·23 to 0·01)	..	−0·14 (−0·26 to −0·02)	..	−0·08
Peer problems	1·92 (0·04)	1·78 (0·05)	−0·11 (−0·21 to −0·02)	..	−0·10 (−0·20 to −0·02)	..	−0·08
Pro-social strengths	6·91 (0·10)	7·09 (0·10)	0·07 (−0·04 to 0·18)	..	0·08 (−0·02 to 0·19)	..	0·06
SWEMWBS total wellbeing index	22·88 (0·19)	23·32 (0·19)	0·27 (−0·06 to 0·60)	0·1150	0·33 (0·00 to 0·66)	0·0487	0·07
Age of sexual debut	13·11 (0·43)	12·54 (0·49)	−0·58 (−1·97 to 0·81)	0·4155	−0·35 (−1·48 to 0·78)	0·5409	−0·12
Modified aggression scale, bullying subscale	2·75 (0·21)	2·33 (0·21)	−0·28 (−0·84 to 0·29)	0·3333	−0·26 (−0·57 to 0·05)	0·0976	−0·12

GBS=Gatehouse Bullying Scale. ESYTC=Edinburgh Study of Youth Transitions and Crime. PedsQL=Paediatric Quality of Life Inventory. SDQ=Strengths and Difficulties Questionnaire. SWEMWBS=Short Warwick Edinburgh Mental Wellbeing Scale. *Shows the number of students who responded at this survey; actual number of responses to each question varied, but non-response for each item was similar across arms. †Does not include the pro-social score subscale.

Table 3: Continuous secondary outcomes

	Control group (3087 students)*	Intervention group (2281 students)*	Unadjusted odds ratio (95% CI)	p value	Adjusted odds ratio (95% CI)	p value	Adjusted risk difference (95% CI)	p value
Ever smoked regularly								
No	2293 (77.70%)	2318 (84.17%)	1.00	0.0011	1.00	0.0009	..	0.0006
Yes	658 (22.30%)	436 (15.83%)	0.59 (0.43 to 0.81)	..	0.58 (0.43 to 0.80)	..	-0.03 (-0.05 to -0.01)	..
If yes, how long since last smoked	1.46 (1.06 to 2.01)†	..	1.40 (1.02 to 1.93)†
<1 day	105 (16.20%)	49 (11.56%)
1-3 days	61 (9.41%)	26 (6.13%)
4-7 days	37 (5.71%)	24 (5.66%)
1 week-1 month	85 (13.12%)	57 (13.44%)
1-2 months	63 (9.72%)	50 (11.79%)
3-6 months	87 (13.43%)	69 (16.27%)
>6 months	210 (32.41%)	149 (35.14%)
Ever drunk alcohol?								
No	1677 (56.43%)	1735 (62.43%)	1.00	0.0290	1.00	0.0094	..	0.0082
Yes	1295 (43.57%)	1044 (37.57%)	0.75 (0.58 to 0.79)	..	0.72 (0.56 to 0.92)	..	-0.03 (-0.06 to -0.01)	..
If yes, had alcohol in the past week
No	949 (75.80%)	800 (80.00%)	1.00	..	1.00
Yes	303 (24.20%)	200 (20.00%)	0.71 (0.52 to 0.98)	..	0.67 (0.50 to 0.91)
Number of times really drunk	0.57 (0.33 to 0.98)†	0.0426	0.51 (0.33 to 0.80)†	0.0029
Never	788 (53.14%)	721 (61.21%)
Once	283 (19.08%)	178 (15.11%)
2-3 times	221 (14.90%)	144 (12.22%)
4-10 times	124 (8.36%)	67 (5.69%)
>10 times	67 (4.52%)	68 (5.77%)
Binge drinking (≥5 drinks in a row) in past 30 days								
0	1162 (73.97%)	974 (76.57%)
1-2	276 (17.57%)	209 (16.43%)
3-5	69 (4.39%)	45 (3.54%)
6-9	30 (1.91%)	13 (1.02%)
≥10	34 (2.16%)	31 (2.44%)
Ever been offered illicit drugs								
No	1913 (64.41%)	1997 (72.54%)
Yes, but did not try them	744 (25.05%)	567 (20.60%)
Yes, and tried them	313 (10.54%)	189 (6.87%)
Used any contraception at first sex								
No	64 (23.10%)	36 (21.95%)	1.00	0.6583	1.00	0.8410	..	0.8395
Yes	213 (76.90%)	128 (78.05%)	1.18 (0.56 to 2.48)	..	1.08 (0.50 to 2.35)	..	0.01 (-0.08 to 0.10)	..
Use of NHS services in past 12 months								
No	1605 (53.22%)	1472 (52.59%)	1.00	0.6392	1.00	0.5652	..	0.5647
Yes	1411 (46.78%)	1327 (47.41%)	0.96 (0.83 to 1.12)	..	0.96 (0.82 to 1.11)	..	-0.01 (-0.04 to 0.02)	..
Contact with police in past 12 months								
No	2626 (86.52%)	2485 (88.43%)	1.00	0.0403	1.00	0.0269	..	0.0222
Yes	409 (13.48%)	325 (11.57%)	0.75 (0.57 to 0.99)	..	0.74 (0.56 to 0.97)	..	-0.02 (-0.04 to -0.003)	..

All assessed at 36 months. Data are n (%), unless stated otherwise. NHS=National Health Service. *The number of students who responded at this survey; actual number of responses to each question varies, but item non-response is similar across arms. †Proportional odds ratio.

Table 4: Categorical secondary outcomes

the intervention group who had ever smoked, there was evidence that the time since the last cigarette was longer than in those in the control group and that, among those who had ever drunk alcohol, there were lower odds of having drunk in the past week, and number of

times having been really drunk (table 4). Students in intervention schools had lower odds of having ever been in contact with police in the past 12 months than did those in control schools (table 4). We found no evidence of differences in age of sexual debut or use of

contraception at first sex, bullying perpetration, or use of NHS services. The appendix shows results for secondary outcomes at 24 months not selected for formal testing (pp 10–13).

Subgroup analyses suggest that the intervention had a greater effect in boys than in girls for many secondary outcomes (quality of life, psychological problems, wellbeing, having ever smoked regularly, having ever drunk alcohol, bullying perpetration, and contact with police; table 5). The intervention was also more effective in students with higher baseline bullying experience, with greater effects on bullying and psychological problems, quality of life, and wellbeing (table 5). The intervention was more effective in those with greater baseline aggression, with greater effects on both primary outcomes (bullying victimisation and aggressive behaviour), psychological secondary outcomes (quality of life, psychosocial problems, and wellbeing) and some risk behaviours (ever smoked regularly, ever drunk alcohol; table 5). There was no suggestion of any difference in the outcomes by socioeconomic status (appendix pp 14–15).

Other process evaluation findings will be reported elsewhere. Fidelity to the intervention varied between schools and over time, with a reduction in the fidelity of formal intervention activities in the third year. The median fidelity score for the first and second years was 6 out of 8 (IQR 5–7), whereas for the third year the median was 1 out of 4 (IQR 0–3). In the third year, 15 schools sustained restorative practice. Interviews with action group members and focus groups with staff in case-study schools suggested that in the third year, schools commonly incorporated what they regarded as the most useful action group functions into mainstream school structures and processes. Training, action groups, and restorative practices but not the curriculum were delivered with good fidelity (appendix pp 23–24). Increased fidelity of delivery in the first 2 years of the intervention was associated with lower bullying victimisation at 24 months but not with lower aggression (appendix p 17). The fidelity score in the third year was not associated with either primary outcome (appendix p 17).

Slightly over half of staff in intervention schools were aware that the school had been taking steps to reduce bullying and aggression, falling slightly between the second and third years (appendix pp 18–19). About a third of students reported being aware that the school had been taking steps to reduce bullying (appendix pp 20–21). About half reported that if there was trouble at school, staff responded by talking to those involved to help them get on better. About two-thirds of students reported that teachers and students got together to build better relationships or discuss their views and feelings. Other data on the process evaluation are shown in the appendix (pp 22–29).

Many schools in the control group implemented similar activities to those prescribed in the intervention but with

variable degrees and quality. Five control schools used restorative practice, social and emotional skills education, and consultation with students on policy. A per protocol analysis excluding these schools showed no discernible differences in the intervention effects compared with the intention-to-treat analyses (appendix p 30).

The main time-consuming activities for school staff were attending the training and curriculum delivery. We included staff training in the intervention costs but staff interviews suggested that training was not additional but part of existing training periods, suggesting that the intervention costs might be overestimated. Mean total costs to the education sector to address bullying were £116 per pupil (SD 47) in the control group compared to £163 per pupil (SD 69) in the intervention group over the first 2 years, and £63 (33) versus £74 (37) in the third year. For the intervention schools, the mean cost of facilitators and trainers was £11039 per school (SD 993). The mean cost to address bullying per school of all staff time combined was £232670 (SD 113634) for the intervention group and £202405 (SD 103090) for the control group. Costs for health-service use and police contacts were similar in both groups (appendix p 34). Overall, the intervention increased costs and reduced bullying, leading to incremental costs averted of £2352 at 36 months. Further details of resource use and costs are reported in the appendix (31–34).

The number of reported serious events was similar in each group although patterns differed (table 6). Two each of suicide and stabbing incidents were reported by intervention group schools, which could reflect increased reporting in intervention schools.

Discussion

We report results of the first randomised controlled trial of restorative approaches to reduce bullying and aggression and promote student health, using a whole-school approach, engaging students in school decision making, and providing social and emotional skills education. Learning Together reduced student reports of bullying victimisation compared with schools continuing their standard practice. We did not identify a reduction in overall student reports of aggression. Learning Together seemed to have larger benefits for many secondary outcomes, from improved psychological function, wellbeing, and quality of life, to reductions in police contact, smoking, and alcohol and drug use. The effects on bullying and other continuous outcomes by the third year approximated 0.1 SD, which could be important at the population level. We found intervention effects both in the whole sample and in schools with higher levels of bullying or aggression at baseline, implying that the intervention worked to curtail existing bullying and aggression (secondary prevention) as well as prevent new bullying (primary prevention). We also found that the Learning Together intervention had greater effects for boys than in girls for secondary psychological and

	Main adjusted effect		By sex		By baseline bullying			By baseline aggression				
	Effect size*	p value	Boys (95% CI)		Girls (95% CI)	P _{interaction}	Low (95% CI)	High (95% CI)	P _{interaction}	Low (95% CI)	High (95% CI)	P _{interaction}
Continuous outcomes												
GBS overall score	-0.03 (-0.06 to -0.001)	0.0441	-0.04 (-0.08 to 0.001)	-0.03 (-0.06 to 0.01)	0.6113	0.15 (0.12 to 0.18)	-0.41 (-0.45 to -0.36)	<0.0001	0.01 (-0.03 to 0.05)	-0.06 (-0.10 to -0.02)	0.0024	
ESYTC overall score	-0.13 (-0.43 to 0.18)	0.4199	-0.33 (-0.73 to 0.06)	0.04 (-0.32 to 0.39)	0.0890	0.02 (-0.34 to 0.37)	-0.17 (-0.63 to 0.29)	0.4422	0.71 (0.33 to 1.10)	-0.65 (-1.03 to -0.27)	<0.0001	
PedsQL overall score	1.44 (0.70 to 2.17)	0.0001	3.85 (2.89 to 4.80)	-0.41 (-1.28 to 0.46)	<0.0001	0.34 (-0.52 to 1.19)	3.93 (2.81 to 5.04)	<0.0001	-0.14 (-1.13 to 0.85)	2.70 (1.74 to 3.65)	<0.0001	
SDQ total difficulties score	-0.54 (-0.83 to -0.25)	0.0002	-1.29 (-1.67 to -0.92)	0.04 (-0.30 to 0.39)	<0.0001	-0.08 (-0.42 to 0.26)	-1.61 (-2.05 to -1.17)	<0.0001	0.34 (-0.05 to 0.72)	-1.31 (-1.69 to -0.94)	<0.0001	
SWEMWBS total well-being index	0.33 (0.00 to 0.66)	0.0487	1.32 (0.89 to 1.74)	-0.42 (-0.81 to -0.04)	<0.0001	0.14 (-0.24 to 0.53)	0.93 (0.43 to 1.43)	0.0034	-0.18 (-0.62 to 0.26)	0.78 (0.36 to 1.21)	0.0001	
Age of sexual debut (years)	-0.35 (-1.48 to 0.78)	0.5409	-0.63 (-1.99 to 0.74)	0.01 (-1.51 to 1.53)	0.4879	-0.14 (-1.34 to 1.05)	-0.46 (-1.89 to 0.98)	0.7085	-0.63 (-2.40 to 1.15)	-0.42 (-1.58 to 0.73)	0.8308	
Modified aggression scale score	-0.26 (-0.57 to 0.05)	0.0978	-0.53 (-0.89 to -0.18)	-0.03 (-0.37 to 0.31)	0.0029	-0.18 (-0.52 to 0.17)	-0.22 (-0.62 to 0.18)	0.8100	0.03 (-0.33 to 0.39)	-0.25 (-0.60 to 0.10)	0.0933	
Categorical outcomes												
Ever smoked	0.58 (0.43 to 0.80)	0.0009	0.33 (0.22 to 0.50)	0.87 (0.60 to 1.25)	<0.0001	0.66 (0.46 to 0.96)	0.52 (0.33 to 0.80)	0.2887	0.93 (0.58 to 1.49)	0.46 (0.32 to 0.68)	0.0053	
Ever drunk alcohol	0.72 (0.56 to 0.92)	0.0094	0.52 (0.38 to 0.70)	0.95 (0.71 to 1.26)	0.0002	0.81 (0.61 to 1.07)	0.57 (0.41 to 0.81)	0.0541	1.08 (0.78 to 1.49)	0.56 (0.41 to 0.75)	0.0009	
Been offered illicit drugs	0.51† (0.36 to 0.73)	0.0003	0.44† (0.29 to 0.68)	0.57 (0.38 to 0.86)	0.2350	0.46† (0.31 to 0.68)	0.58† (0.37 to 0.93)	0.2895	0.62† (0.40 to 0.96)	0.50† (0.34 to 0.74)	0.3137	
Used any contraception at first sex	1.08 (0.50 to 2.35)	0.8410	1.02 (0.39 to 2.69)	1.19 (0.36 to 3.90)	0.8409	0.55 (0.20 to 1.57)	2.63 (0.61 to 11.35)	0.0905	0.18 (0.02 to 1.45)	1.35 (0.45 to 4.13)	0.1003	
Use of NHS in past 12 months	0.96 (0.82 to 1.11)	0.5652	0.96 (0.79 to 1.17)	0.95 (0.80 to 1.14)	0.9590	0.96 (0.81 to 1.16)	1.02 (0.80 to 1.29)	0.6717	1.12 (0.90 to 1.38)	0.93 (0.76 to 1.14)	0.1556	
Contact with police in past 12 months	0.74 (0.56 to 0.97)	0.0269	0.62 (0.45 to 0.85)	0.93 (0.66 to 1.31)	0.0371	0.66 (0.48 to 0.92)	0.79 (0.53 to 1.17)	0.4280	0.93 (0.58 to 1.47)	0.67 (0.49 to 0.93)	0.1917	

Low and high baseline bullying were defined on the basis of the GBS. High was defined as at least weekly experience of bullying or being upset by it, low was defined as less than weekly experience of bullying and not being upset by it. Low and high aggression were defined on the basis of the ESYTC school misbehaviour subscale, with high levels of behaviour problems defined as scores >0 and low levels defined as scores of 0. GBS=Gatehouse Bullying Scale, ESYTC=Edinburgh Study of Youth Transitions and Crime, PedsQL=Pediatric Quality of Life Inventory, SDQ=Strengths and Difficulties Questionnaire, SWEMWBS=Short Warwick-Edinburgh Mental Well-Being Scale, NHS=National Health Service. †Effects are difference (95% CI) for continuous outcomes and odds ratios (95% CI) for categorical outcomes. ††Proportional odds ratio.

Table 5: Subgroup analyses at 36 months

	Control group (n=20)	Intervention group (n=20)
Suicide	0	2
Responses showing potential for self-harm	0	4
Stabbing incidents	0	2
Possible non-consensual sex (including age <10 years)	6	0
Disability or long-term illness	1	0
Total	7	8

Reported at the school level (any relevant events in any student) or student level (from survey responses).

Table 6: Serious adverse events

behavioural outcomes, although not for primary outcomes. The intervention was cheap, falling into the very low cost category for UK school interventions.⁴⁶ The costs of trainers, facilitators, and school staff were an additional £47–58 per pupil in the intervention group compared with control schools over the 3 years.

We found an effect of the intervention on bullying at 36 months (as hypothesised for our primary outcome) but not at 24 months, and we found a similar strengthening of effects over time for most secondary outcomes. This probably reflects the time needed for components of the intervention to be translated into organisational change within schools, consistent with evidence from the Gatehouse Project, a previous trial of an intervention to modify the whole-school environment to reduce health risk behaviours among Australian adolescents.⁴⁷ Although many schools did not deliver formal intervention components so well in the third year as earlier, our process evaluation suggested that by the third year schools had integrated components of the intervention into mainstream school structures and processes.

We found no effect on perpetration of aggressive behaviours, contrary to a study by Flay and colleagues,²² although consistent with the Gatehouse study⁴⁷ and findings from reviews, which suggest that school-based studies of bullying prevention interventions consistently have stronger effects on victimisation than on perpetration.¹⁸ The Gatehouse Project showed no effect on bullying or psychological problems, by contrast with our findings,²¹ although it did show similar effects on risky behaviours including substance use.⁴⁷ As predicted by our theory of change,²⁰ intervention effects were concentrated on behaviours that could be markers of disengagement from school, such as bullying, smoking, and drunkenness. We found no effects on sexual health outcomes, perhaps because our intervention did not explicitly address sexual health, or because, unlike bullying and substance use, sexual behaviours occur off the school site and in private.

In terms of strengths, participating schools were representative of the approximately 500 schools initially approached and all schools were retained in the trial. Our follow-up was sufficiently lengthy to allow both time for intervention effects to develop and investigation of

persistence of intervention effects after the end of the facilitated intervention. Student participation was high. Our outcome research team and intervention team remained independent throughout the trial and masking of lead researchers, fieldworkers, and analysts was maintained. We assessed outcomes using age-appropriate validated instruments. Although self-reported outcomes can be open to recall bias, we collected baseline data before randomisation, used instruments with standardised recall periods, and actions at the school-level are unlikely to have biased reporting between intervention and control groups.

In terms of limitations, absence of students at baseline or at some follow-up points could have introduced bias. However, if non-responders are more likely to have experienced bullying or behaviour problems, this limitation is likely to have underestimated the intervention effect. The large number of secondary outcomes investigated necessitated multiple statistical testing. To mitigate the weakness of this, we only tested prespecified secondary and subgroup analyses. Had we applied an overly conservative Bonferroni correction, four of the secondary outcomes (paediatric quality of life score, strengths and difficulties score, ever smoked regularly, ever been offered illicit drugs) would have remained significant (data not shown). Some schools in the control group implemented activities that resembled some elements of Learning Together intervention. However, only five control schools implemented activities that resembled the three key elements of the intervention (restorative practice, social and emotional skills education, and student participation in decision making) and a per-protocol analysis excluding these control schools found similar intervention effects. A sensitivity analysis excluding the six schools selected for more intensive process evaluation showed no discernible differences in intervention effects compared with the intention-to-treat analyses (data not shown).

Our study adds to the evidence that whole-school approaches to prevent bullying and aggression, and promote student health are feasible and have positive effects on a range of outcomes in a broad range of high-income, middle-income, and low-income settings.^{18,21–23} Learning Together offers the potential for broad improvements in behaviour and health in secondary schools and the results of this trial provide strong support for further development of restorative approaches in secondary schools. The findings are important for public health policy in that a single, very low cost intervention affected a related set of outcomes of public health importance. The findings provide the first experimental evidence that multiple health outcomes can be promoted by transforming the school environment and increasing educational engagement.

We found positive effects of Learning Together despite variable fidelity to the intervention. For such organisational-change interventions, traditional fidelity of form (what intervention components were delivered)

might be less important than overall fidelity of function (whether overall the intervention triggered the mechanisms in the ways theorised, albeit in locally appropriate ways).⁴⁸ Our findings are particularly encouraging given that many of the control schools were delivering broadly similar activities, including restorative practice and student involvement in decision making, suggesting that Learning Together packaged and promoted these activities more effectively than most schools could do on their own.

The poor fidelity for the curriculum element suggests this aspect was less likely to have contributed significantly to the benefits of Learning Together. Given that participating schools were representative of those invited for participation and included a good range in terms of attainment, deprivation, and inspectorate ratings, Learning Together could have similar effects in other schools in England and beyond. The wider value of Learning Together should be examined in further trials in diverse settings.

At a time when the mental health of young people is a major public health concern internationally,^{17,49} countries such as the UK⁷ and Australia⁴⁹ have identified schools as a key part of improving mental health. Interventions to promote student health by modifying the whole-school environment, such as Learning Together, are likely to be one of the most efficient ways of promoting mental health and wellbeing while also addressing other health harms in adolescence, because of their potential to modify population-level risk and their wide reach across health outcomes and likely sustainability.⁵⁰

Contributors

RMV and CB led development of the Learning Together intervention, had the idea for the study, designed the trial, led the evaluation. RMV, AM (trial manager), LBe, and JM evaluated outcomes. CB led the process evaluation and intervention teams. EA and DE designed the trial. EA and CO did the statistical analysis. JS managed the trial data and did the analysis. FJ and EW did the process evaluation. RL and ZS did the economic analysis. AF, LBo, and MW developed the intervention. SS and DC contributed to contributed towards the choice and interpretation of outcomes relating to psychological problems and mental wellbeing. All authors with the exception of FJ wrote the report.

Declaration of interests

CB, LG, JS, EA, EW, JM, LB, RL, MW, CO, AM, JS, AF, ZS, DE, LB, SS, and RMV declare no competing interests. RMV is President of the Royal College of Paediatrics & Child Health. DC has received personal fees from Medtronic, Pfizer, and ASCEND.

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