INCLUSIVE PILOT TRIAL PROTOCOL

Date: **28 November 2011**

Version: **1.1**

Title: **INCLUSIVE trial: Initiating change locally in bullying and aggression through the school environment**

Funder: **National Institute of Health Research HTA** (reference 09/05/05)

Research Objectives

The overall objective of the INCLUSIVE investigators is to examine the delivery, effectiveness and cost effectiveness of a multi-component universal school-based intervention to reduce aggressive behaviours in adolescents.

Pilot trial objective: To assess the feasibility and acceptability of planning and delivering the INCLUSIVE intervention and trial methods to inform a full-scale trial.

Pilot trial design

Study design: Cluster randomised controlled pilot trial (MRC complex intervention phase II exploratory trial) of 8 schools (4 intervention, 4 comparison).

Setting: Mixed-sex state secondary schools in southern/central England with ≥6% of students eligible for free school meals (FSM). Schools purposively sampled to ensure diversity with regard to most recent Ofsted-rating of school effectiveness and overall rate of eligibility for FSM.

Target population: 11-16 year olds in school. Note, although the intervention will target the whole school, only students in Year 8 (aged 12-13) will be surveyed.

Allocation: Four clusters (schools) will be randomly allocated to the intervention arm and four to the comparison arm.

Process evaluation and evaluation of mechanism of action: The primary objective of the pilot trial is to assess feasibility and acceptability and therefore the primary outcome of interest is the feasibility of recruitment and delivery of the intervention. Quantitative and qualitative data will be collected and analysed to assess implementation, evaluate feasibility, fidelity and acceptability, and explore causal pathways (the **Appendix** provides further details of these methods).

Outcome evaluation: The indicative primary outcome measure being field-tested in this pilot trial is aggressive behaviour (measures to be piloted via baseline surveys). Outcomes will be measured at baseline (September 2011) and again at the end of the school-year (July 2012) via surveys of Year 8 students.

Primary analytic aim: to evaluate feasibility and acceptability via the process evalaution data.

INCLUSIVE intervention

Summary

Schools will be randomized to the INCLUSIVE intervention or the comparison group (i.e. continue with normal practice). Below, we summarise our multi-component INCLUSIVE intervention, to be piloted over the 2011/12 school year.

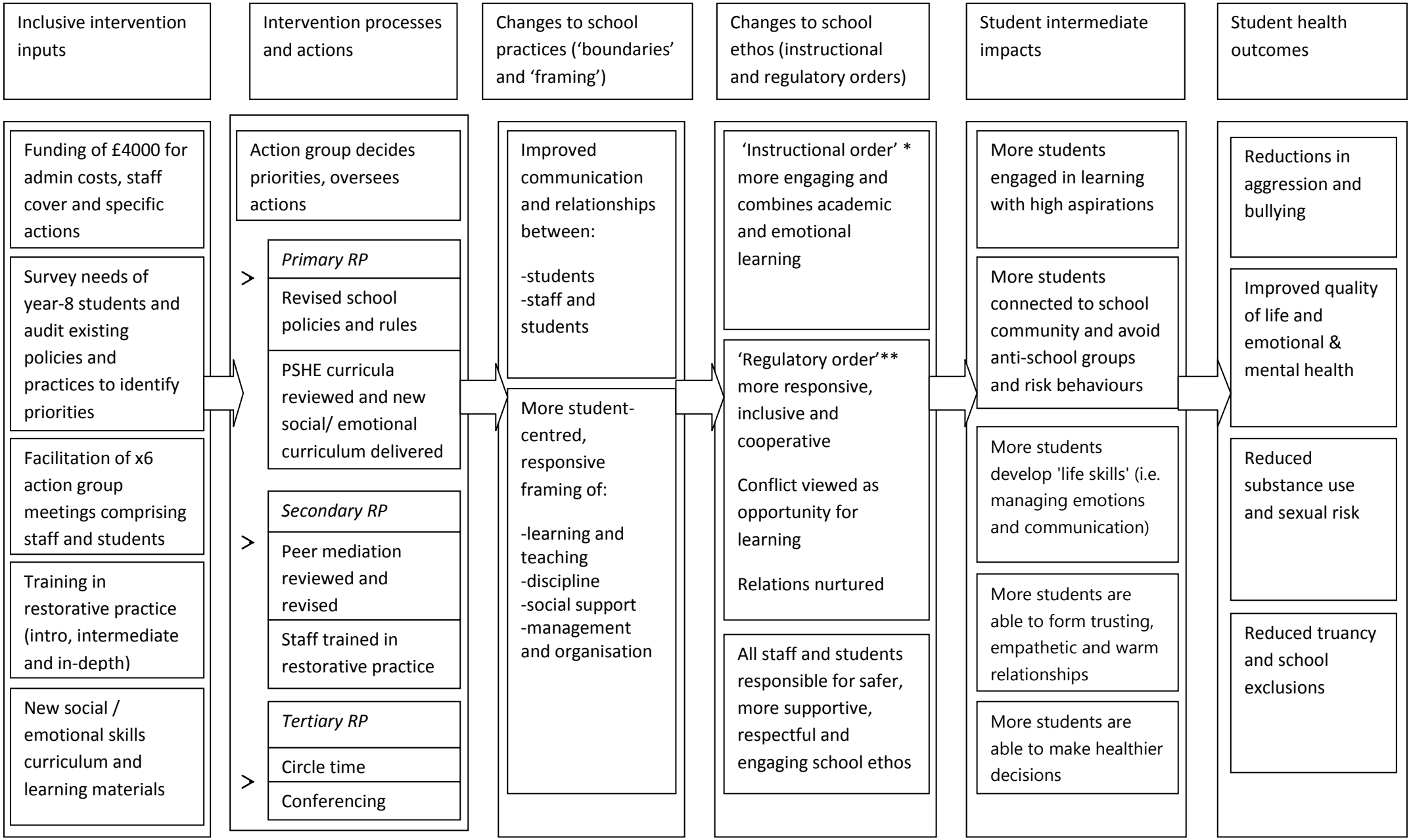
INCLUSIVE is a 'school-environment' (SE) intervention that is strongly informed by the Gatehouse Project from Australia[1] and the Aban Aya Youth Project (AAYP) from the USA[2]. The Gatehouse Project was led by LB (an investigator on this proposal) and GP (a collaborator). AAYP was led by BF (a collaborator). We have modified these previous interventions and aim to more effectively reduce aggression and bullying in schools by promoting the use of 'restorative' practices across the school to promote a safe, supportive, respectful and engaging school environment. While the whole-school changes that arise from the intervention are intended to benefit all students within each school, our evaluation focuses on the cohort in Year 8 (see '**Recruitment**' below).

Our intervention consists of provision of: funding; a needs assessment survey; an external expert facilitator; staff training in restorative practices; and a social/emotional skills curriculum. These are the INCLUSIVE intervention *inputs* (see **Figure 1: intervention logic model**). These enable schools to convene an Action Group, identify priorities and support the intervention *processes*: reviewing and revising school policies and rules; enhancing peer mediation schemes; the implementation of restorative practices, including 'circle time' and conferencing; as well as, a student curriculum. These are hypothesised to lead to a reduction in aggressive and other health-risk behaviours according to our 'logic model' (see below).

Our intervention will allow some tailoring of what is delivered in each school according to student need, informed by our needs-assessment survey and other local data sources. This balancing of standardisation and flexibility is common practice in SE interventions, and in other complex interventions. In the case of SE interventions, this scope for local flexibility allows schools to build on their current good practice (rather than ignoring or having

[1] Bond L, et al (2004) The Gatehouse Project: can a multi-level school intervention affect emotional well-being and health risk behaviours? *Journal of Epidemiology and Community Health*, 58: 997-1003.
[2] Flay B, et al (2004) Effects of 2 Prevention Programs on High-Risk Behaviors Among African American Youth. A randomized trial. *Archives of Paediatric and Adolescent Medicine*, 158, 377-384.

Figure 1: intervention logic model



* i.e. learning and teaching in school ** i.e. discipline, social support and sense of community in school

to ‘reinvent’ what they do) and also encourages students and staff to develop ownership of the work. To facilitate this, the facilitator will ensure broad participation on our Action Group.

The pilot study will assess the feasibility and acceptability of planning and delivering the facilitated intervention over 1 year. As a result of piloting, our intervention theory and logic model is likely to undergo some modification prior to the full trial. For a subsequent full trial, we have proposed a longer-term, 3-year intervention: the first two years of this will be a fully-facilitated intervention as in the pilot study (i.e. schools are supported by additional funding, facilitation, training, etc.). The third year of intervention would require schools to continue with the intervention without these additional resources to assess its sustainability in the absence of facilitation (in order to gauge what period of facilitation would be optimal should the INCLUSIVE intervention be mainstreamed).

Intervention inputs

(1) Funding: Each school Action Group will receive £4000 to cover schools’ administrative costs, provide cover for staff involvement and fund specific actions to support change (e.g. training and equipment for peer mediators, convening student ‘away days’ to revise school rules, etc.). Note these funds are in addition to the costs of the external facilitator whose services are provided to intervention schools free of charge as part of this project. Use of the funds will largely be determined by the Action Group, with financial responsibility taken by school leadership team (SLT) members.

(2) Needs assessment: We will use our baseline survey of students in Year 8 to assess prevalence (overall and by gender) of aggression, bullying, feelings of safety and social support, school disengagement and difficulties at school. Findings will be discussed by the Action Group and used to build commitment, determine local priorities and inform-making.

(3) INCLUSIVE facilitator: Schools will be supported by an expert facilitator (a freelance education consultant with previous secondary school leadership experience). This individual will coordinate the intervention in each school through holding preliminary meetings with the SLT, school staff and students to build interest and trust. The facilitator will also: convene and support the Action Group (see Input #4 below) to ensure broad participation, critical reflection and effective delivery; organise the staff training and tailor this to schools needs; assist schools to integrate a ‘restorative’ approach within all existing policies and practices; work with schools to adapt and integrate the INCLUSIVE curriculum (see Input #5 below) into the school timetable and existing lesson plans; and, provide school leaders with ongoing, informal support and feedback.

(4) Staff training in restorative practice (RP) approaches: the facilitator will provide introductory RP training to all staff in the school. Further training will be provided to approximately 20 staff in each school on the use of specific restorative practices such

as circle time and peer observation of each other's classroom management. The aim is for these teachers to introduce new practices, such as 'circle-time', during registration and/or other lessons to promote positive relationships and bring students together with their teacher. We will also provide enhanced restorative justice conferencing training for approximately 5 staff. Restorative conferencing will be used to deal with more serious incidents and bring together relevant staff, students, parents and, where necessary, external agencies. Training in delivering the INCLUSIVE curriculum will also be provided to those staff identified to deliver this if necessary (see Input #5 below).

(5) INCLUSIVE curriculum delivery: students in Year 8 will receive an additional 6-10 hours teaching and learning focused on social and emotional knowledge and skills, drawing on the Gatehouse Project curriculum[3], as well as an introduction to restorative practices. Modules will cover: establishing respectful relationships in the classroom and wider school; managing emotions; understanding and building trusting relationships; exploring others' needs and expectations and avoiding conflict; and maintaining and repairing relationships. Sessions will include information giving, discussion and practical workshops, etc. The facilitator will work with the school managers to facilitate the integration of the INCLUSIVE curriculum resources within the school timetable and existing lesson plans. It may be delivered as 'stand-alone' lessons, for example within 'Personal, Social and Health Education' (PSHE) and/or integrated into various subject lessons.

School Action Group

The Action Group will be a key agent of change within the school. It is likely to be a new group but may arise from a modification of an existing school body. It will comprise (at a minimum): 6 students; and 6 staff, including at least 1 senior leadership team (SLT) member, and 1 member of each of the teaching, pastoral and support staff. Membership of specialist health staff, such as the school nurse and/or local child and adolescent mental health (CAMHS) staff, is desirable but optional and will be reviewed locally.

The Action Group will meet at least 6 times over the school year. The team will: review data on needs to determine priorities; review and revise existing school policies and practices (e.g. discipline, bullying, pastoral care, etc.) according to restorative principles; develop an action plan for the year, with milestones for delivering specific outputs and a nominated 'lead' person for each one; and review progress and ensure delivery.

The Action Group will also review and (where necessary) revise existing peer-mediation/peer-support schemes, ensuring these are aligned with restorative principles and practices. The INCLUSIVE facilitator will also work with the Action Groups and SLT to ensure that peer mentors receive enhanced training and

[3] Glover S, et al. (2001) Gatehouse Project: Teaching Resources for Emotional Well-being. Victoria, Australia: the Centre for Adolescent Health.

supervision, including in indications/contra-indications for intervening in disputes (to ensure they do not intervene when it would be more proper to seek assistance from staff) and ongoing monitoring and support to ensure their participation does not lead to their being targeted by aggressors (and appropriate staff intervention if this does occur).

School Action Groups will also be encouraged to undertake other locally determined actions which they believe may improve school environment and safety, such as zoning school space for use by specific year-groups, or improving pastoral care arrangements or student rewards. More generally, this intervention also aims to promote the incorporation of a restorative approach into the whole school setting through the everyday language and practices of the school. The Action Group will also have an important role in doing this.

Recruitment and randomization

Eight schools will be recruited by the educational facilitators.

Recruitment criteria

Schools: State secondary schools in southern/central England purposively sampled to ensure diversity according to Ofsted-rating of school effectiveness and overall rate of eligibility for free school meals (FSM). **Table 1** explains the diversity and matching criteria for recruiting schools. Independent schools; and, schools with 6% or fewer students eligible for FSM (least deprived 15% of schools) are not eligible for inclusion.

Table 1: diversity and matching criteria

		Most recent Ofsted-report rating	
		Satisfactory	Good/outstanding
Eligibility for free school meals in 2010	Average/Below the national average	2 schools	2 schools
	Above the national average	2 schools	2 schools

Students: While the intervention addresses the whole school, we will only collect data from young people in Year 8 (aged 12-13) at baseline in both the pilot and full trial. We will attempt to include those not in schools on the day of the survey by leaving their questionnaire in a stamped-addressed envelope for them to return to the research team at LSHTM at a later date.

Randomisation

Randomisation will occur after all student baseline surveys have taken place at the schools. Each school within each 'matched pair' (see **Table 1** above) will be randomly

allocated the number 1 or 2 and then the school numbered 1 will be allocated to either the intervention or control arm using random number generation (intervention if n>0.5; control arm if n<=0.5). Although schools and students are not 'blind' to their allocation status, fieldworkers and data-input staff will be 'blinded' as to each school's status throughout the study.

Compliance, retention and loss to follow-up

School level: To promote implementation we will ask the head-teachers and the chair of governors at participating schools to sign a letter of agreement before randomization to the intervention or the comparison arm. We will ensure schools that are allocated to receive the intervention develop and agree a detailed action plan (i.e. addressing all intervention components) in Term 1 of the project, with the detailed plan actions and timelines informed by the needs-assessment data from that school and reviewed at meetings at least once every half-term throughout the academic-year.

Schools allocated to the comparison group will continue with standard practice and receive no additional input. Our experience from previous school trials is that retaining those schools allocated to the comparison group can be an issue. We anticipate that comparison-group-school participation will be enhanced by randomisation after the baseline survey but we will also use a number of techniques to minimise loss to follow-up of control schools:

- Payment of £500 to control schools to support the study occurring in the school, contingent on them ensuring that a senior staff-member acts as our liaison;
- Ensuring that experienced researchers liaise with comparison schools;
- Feedback of survey data to comparison schools after completion of the study if requested (e.g. schools highly value data which can be used to monitor and change policy and practice after completion of the study).

We are also aware that schools are involved in many whole-school and curriculum initiatives to provide a supportive learning environment for students, including policies and practices to reduce violence in schools (e.g. bullying policies, discipline approaches etc), and student personal development curricula, *some* of which may overlap with *some* of the activities we propose in the intervention schools. As part of the process evaluation (see **Appendix**), we will document current policies and practices related to aggressive behaviour, bullying, substance use and health more generally, and the curricula materials they use for PHSE (and why). There will not be a requirement that they avoid implementing practices similar to those contained in our intervention.

Student level: We will attempt to obtain data from those absent on the day of survey via leaving their questionnaire in a stamped-addressed envelope for them to return to the research team at LSHTM at a later date.

Power calculation and sample size

This is a pilot study and thus no power calculations for the primary outcome(s) of interest have been performed: the primary analytic aim is to evaluate feasibility and acceptability via the process evaluation data. We will recruit 8 schools with approximately 150 students per school-year cohort and randomly allocate 4 to the intervention arm and 4 to the comparison group. We will only measure individual outcomes among a cohort of students who are in Year 8 (age 12-13 years) in 2011/2. Thus the total student sample for the pilot study will be approximately 1200 students. Participation rates in the survey are estimated to be 80-90% from our previous experience.

Data collection

The primary outcome of interest is feasibility of recruitment and delivery of the intervention. Analysis of process not outcome data will be the primary focus of this pilot trial in order to assess whether it would be appropriate to continue to a full trial by establishing whether the following conditions are met:

Criteria 1: Was it feasible to implement the intervention in (at least) 3 out of 4 intervention schools? This will be assessed according whether:

- The needs-assessment survey had a 80%+ response rate;
- the Action Group (AG) met 6 times during the course of the school year and was always quorate (i.e. minimum of 2/3^{rds} members present);
- the AG reviewed and revised school policies (e.g. relating to discipline, bullying, pastoral care, peer mediation, etc.);
- whole-school actions (e.g. re-writing school-rules) were a collaborative process involving staff and students from across the school;
- 20+ staff completed restorative practice (RP) training;
- peer mediation and/or 'buddying' schemes were reviewed and 'enhanced';
- Interviews, focus groups and surveys indicate use of restorative practices (RP) (e.g. circle time, restorative conferencing, etc.); and,
- the student curriculum was delivered to year-8 students.

Criteria 2: Was the intervention acceptable to a majority of the school's senior leadership team (SLT) and a majority of AG members?

Criteria 3: Did randomization occur and was this acceptable to school SLTs? Did (at least) 3 out of 4 schools from each of the intervention and comparison arms accept randomization and continue to participate in the study? Were the student survey response rates acceptable at (at least) 3 out of 4 comparison schools?

Process evaluation and evaluation of mechanisms of action data

We will collect and analyse multiple sources of quantitative and qualitative data,

including documentary evidence (e.g. school policies) and facilitator diaries, as well as both quantitative student and staff survey data and qualitative data from interviews, focus groups and observations regarding the feasibility, acceptability, fidelity, and potential mechanisms of action. The **Appendix** provides further details of these methods.

Outcome evaluation

Data will be collected via surveys of Year 8 students at baseline (September 2011) and again at the end of the school-year (July 2012). Paper-based questionnaires will be completed confidentially in classroom conditions in school. Field workers will supervise questionnaire completion, with a teacher present but unable to see the questionnaires. The researchers will assist students with questions they don't understand if they wish, and ensure students complete as much of the questionnaire as possible. Those absent on the day of survey will be asked to return their questionnaires by post.

Indicative primary outcome measure being field-tested in this pilot trial: A future full trial will use aggressive behaviour (physical and/or emotional) as its primary outcome. We include bullying (i.e. repetitive behaviour) within this, and we will measure all aggressive behaviours, both in and out-of-school time. We will use this pilot study to examine the properties (response rates and psychometric properties) of exiting instruments that cover (a) physical violence, (b) emotional abuse (including victimisation) and/or (c) provoking or disrupting behaviours not associated with actual violence. We will adapt and pilot the following two scales:

(1) The Ayan Aba Youth Project (AAYP) sub-scale on aggressive behaviours. We are piloting the following 4-items: Have you ever, or in the past 3 months, (i) threatened to beat someone up, not including your brothers and sisters? (ii) threatened to beat up your brothers and sisters? (iii) threatened to cut, stab or shoot someone? (iv) cut or stabbed someone? Each item is scored 0-3; total score of 12.

(2) The Gatehouse Bullying Scale (GBS) is a short tool to measure the occurrence of victimisation and bullying in schools. The GBS focuses on the experience of bullying and thus potentially complements the AAYP scale. The scale has 12 items, and asks about being the subject of recent (i) teasing and name calling, (ii) rumours, (iii) being left out of things and (iv) physical threats or actual violence from other students. Each section asks about the recent experience of that type of bullying (yes or no), how often it occurred, and how upset the student was by each type of bullying. Unlike other scales which generally ask about bullying in the last year, the GBS asks about 'recent' occurrence of bullying (last 3 months) and is therefore able to assess changes within a school year. As well as a global estimate of bullying the GBS provides estimates of two covert and two overt types of bullying which can be useful for schools to better plan interventions dealing with school bullying.

We will use the pilot study to identify which of these to use as a primary outcome measure for the full trial. Criteria we will use to decide this are: (a) completion rate

(i.e. the proportion of students responding to the questionnaire items and completing each measure in a way that provides usable data); (b) discrimination (i.e. that response options are normally distributed and that students do not opt overwhelmingly for only one of the response options); (c) validity (i.e. interviews and focus group discussions will explore the extent to which students understand the questions). We will use these 3 criteria to identify a single previously validated measure as our primary outcome. The option exists to then retain the second scale as a secondary outcome alongside the other proposed secondary outcomes (below).

Secondary outcomes:

To field-test our secondary outcomes we will also collect data via the Year 8 student surveys on:

1. Quality of life using the 23-item Pediatric Quality of Life Inventory (PedsQL) 4.0 and the Child Health Utility 9D measure.
2. Psychological distress using the Strengths and Difficulties Questionnaire, a brief screening instrument for detecting behavioural, emotional and peer problems and pro-social strengths in children and adolescents.
3. Psychological wellbeing using the (short) Warwick-Edinburgh Mental Well-being Scale.
4. Substance use (point prevalence and recent use of tobacco, alcohol and other drugs).
5. NHS use based on self-reported use of NHS services (primary care, A & E, other) in the past year.
6. Contact with police/justice system based on self-reports of whether stopped, told off or picked up by the police in the past 12 months etc.
7. School disciplinary policies and school environment based on reports of what happens to students in this school if they engage in anti-social behaviours.
8. Truancy based on self-report.
9. School exclusion based on self-report.

Analysis Plan

1. Process evaluation and evaluation of mechanisms of action: Quantitative data from surveys and qualitative data collected via interviews, focus groups and observations and other sources will be integrated and used to examine implementation and uptake, evaluate feasibility, fidelity and acceptability, and explore potential mechanisms of action. As stated above, analyses undertaken in the pilot will inform conclusions about overall feasibility and acceptability, and refinement of our logic model and the intervention itself.

2. Outcome evaluation: all primary and secondary outcome analyses will be carried out according to the principle of intention-to-treat and taking into account clustering at the school level. The data will be analysed by appropriate multivariate regression models, fitting baseline measures of outcomes and other pre-hypothesised potential confounders as covariates. A small number of secondary analyses (e.g. subgroup analyses) based on the a priori logic model/hypotheses and any further hypotheses

which emerge via the analysis of qualitative data will also be undertaken to evaluate mechanisms of action.

3. Economic analyses: Assessing cost-effectiveness is likely to be complicated as the intervention benefits are unlikely to be restricted to standard definitions of 'health' and costs are likely to arise across a number of sectors (e.g. health, education and the criminal justice system). Therefore the objective of the economic analysis within this pilot study will *not* be to perform an evaluation of the intervention per se, but rather to collect evidence and information regarding the design of an appropriate evaluation in preparation for a full trial. For example, the feasibility and desirability of conducting a cost-utility analysis will be examined and compared with other frameworks for evaluation, such as cost-consequence analysis.

Ethical arrangements

Approval has been given by the Research Ethics Committee of the London School of Hygiene & Tropical Medicine (application reference number: 5954).

Risks and benefits

If successful the intervention will result in the following benefits:

1. Reduction of aggression and violence in the school will be of benefit to all participants, the whole school, the local community, and wider society;
2. Reductions in other secondary outcomes (e.g. substance use) as well as improvement in mental health, emotional well-being and quality of life;
3. Reduction in costs to society related to violence and aggression. These include reductions in NHS costs (related to violence and mental health problems), and in social costs including costs within the justice system;
4. Benefits to school staff through increased access to training and an improved school environment, which may improve staff well-being and quality of life;
5. Additional benefits to students who participate in Action Groups, through opportunities for learning, empowerment and improved self-efficacy.

Risks: There are no anticipated risks to participants or to schools. However as in all interventions, there may be unanticipated risks. Our approach may be ineffective, and its introduction in trial schools may prevent the use of more effective techniques to reduce aggression. Although some educational interventions to raise awareness of risk behaviours during adolescence have been shown to increase participation in these behaviours, we believe this is extremely unlikely in the case of this study because as our approach is based upon what is shown to be effective in systematic reviews. Thus, we believe that risks are minimal and that benefits justify the risks.

Informing participants

Details of the research including possible benefits and risks will be provided to schools through written information and personal meetings and provided to student participants through age-appropriate written information.

Consent

Schools: The head-teacher and the chair of governors at participating schools will be asked to sign a participation agreement.

Students: Written consent will be sought from young people. Age-appropriate information sheets will be provided, together with verbal explanation by researchers. Parents who do not wish their child to participate will be able to 'opt-out'. Note that this 'opt-out' consent is acknowledged standard practice for school-based studies in the UK, used by some of our investigator team in school-based intervention (e.g. RIPPLE and HSE) and observation studies (e.g. the RELACHS study).

School staff/facilitators: Written consent will be sought from teachers, other school staff and other facilitators prior to participation.

Data handling and trial documentation

All information will remain confidential within the research team, except where child protection issues are raised. We will consult with a child protection social worker to define what issues will prompt an exemption. The PI (RV), as a paediatrician with training in child safeguarding, will oversee actions where safeguarding concerns are raised, and seek further advice where necessary from appropriate authorities. Relevant trial documentation will be kept for a minimum of 15 years.

Research Governance

We will follow the MRC Guidelines on Good Clinical Practice in Clinical Trials. The PI (RV), the Trial Manager (AF) and the majority of the other investigators have been trained in Good Clinical Practice.

Sponsor: University College London (UCL) is the sponsor of this trial.

Registration: The trial is registered with Current Controlled Trials (www.controlled-trials.com). The International Standard Randomised Controlled Trial Number (ISRCTN) for the pilot study is **ISRCTN88527078**.

Trial Steering Committee (TSC): The trial will be overseen by a TSC, including an independent chair, Prof Rona Campbell, three other independent members, and an investigator representative of each institution involved in the research. Observers from the HTA programme will be invited to all TSC meetings. The TSC will meet 6 monthly throughout the study. The TSC will monitor data for quality and completeness. Missing data will be chased until it is received, confirmed as not available, or the trial is at analysis. Data quality, follow-up and trial monitoring will

be facilitated through the development of a trial specific database, including validation, verification, monitoring and compliance reports and follow up report functionalities. A monitoring schedule will be developed and agreed covering the roles and responsibilities of the Lead Researcher(s), Project Team, Management Committee and TSC for monitoring recruitment, data quality, compliance and safety.

Data Monitoring and Ethics Committee (DMEC): A DMEC is unnecessary as no interim analyses are possible.

Study management: RV will direct the study, together with CB as co-director. The investigator group will meet monthly throughout the study. AF as the trial manager will be responsible for day-to-day operations of the pilot study, and will report to a monthly executive meeting. AF will oversee the general operations of the study and have responsibility for assessment of outcomes and the process evaluation. The operation of the intervention within the schools will be managed by a consultant educational facilitator.

Project timetable and milestones

The study commenced 1 July 2011 and will end 28 February 2013

Month	Milestones
M1-2 set up (July-Aug 2011)	▪ Ethics approval obtained. ▪ Study researcher and educational consultants recruited. Recruitment of 8 schools. ▪ Preparation for baseline surveys: designing and piloting questionnaires, recruitment of field workers, etc.
M3-4 (Sep-Oct 2011)	▪ Recruitment of students in schools and baseline survey. ▪ Randomisation of schools.
M5–12 Intervention (Nov 2011-Jun 2012)	▪ M5: Schools form Action Group (AG); reviews needs-assessment data. ▪ M5-12: AG meets; drafts action plan(s); revises existing policies; nominates staff for training; reviews outcomes. ▪ M6-8: Revision of school rules; staff and enhancement of peer mediator schemes. ▪ M8-12: Implementation of restorative approaches and student curriculum. ▪ Process evaluation and evaluation of mechanisms of actions undertaken throughout intervention.
M12-13 (June-July 2012)	▪ Follow-up survey with students consenting at baseline.
M14-20 Analysis and writing up (Aug 2012-Feb 2013)	▪ M14-15: Data entry and cleaning. ▪ M16-19: Analysis. ▪ M20: Writing of report. ▪ By February 2013 we will be able to submit a proposal to the HTA for funding a full trial.